Rx for Safety
SafeRx Recommendations for Clear and Accessible Prescription Medication

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July 2012
# Table of Contents

Executive Summary...........................................................................................................3
Part One: SafeRx Overview and Frequently Asked Questions..............................5
   I. Overview ................................................................................................................5
   II. Frequently Asked Questions .............................................................................6
Part Two: SafeRx Recommendations ......................................................................9
   I. Pharmacy Primary Languages ........................................................................9
   II. Notification of Rights to Language Services ...............................................11
   III. Mail Order Pharmacies ..................................................................................13
   IV. No Liability for the Actions of Third Parties ...............................................14
   V. Ability to Seek a Waiver ..................................................................................15
   VI. Standardization ...............................................................................................17
   VII. Promoting Language Accessibility on New York State Prescription Pads ....20
Conclusion ..................................................................................................................21
Endnotes ....................................................................................................................22
Appendices ..................................................................................................................24
Executive Summary

Every New Yorker should understand his or her prescription medication labels and should have safe access to prescription medications. Make the Road New York (MRNY), Center for Popular Democracy (CPD) and New York Lawyers for the Public Interest (NYLPI) have championed the issue of safe access to prescription medications in New York State by advocating for the passage of legislation designed to address patient safety. As a result of our efforts, the efforts of Governor Andrew Cuomo’s Medicaid Redesign Team (MRT), and the New York State Legislature, pharmacy language access and label standardization legislation (SafeRx) was passed in the New York State Budget in April 2012. This is the first state law of its kind in the United States, propelling New York as a leader in protecting consumers.

While enactment of SafeRx has been a tremendous victory, the New York State Board of Pharmacy (SBOP), comprised of pharmacy industry representatives, is tasked with developing regulations to implement SafeRx before it goes into full effect. In response, we are producing this report to make recommendations that balance consumer interests with industry interests, and that are based on medical literature and industry best practices. In Part One, our report describes what is required under SafeRx and includes answers to frequently asked questions about SafeRx. In Part Two we discuss our SafeRx recommendations. These recommendations are as follows:

(1) Pharmacy Primary Languages
   - Apply a straightforward approach that requires translation in the top 6 or 7 non-English languages spoken throughout the state, or
   - Use Census and other relevant data to determine the top languages spoken by 1% or more of the limited English proficient (“LEP”) population in a given area, rather than 1% of the general population.

(2) Notification
   - Use a standard message regarding patients’ rights and translate that message in multiple languages (e.g. “I Speak” flash cards in multiple languages).
   - Require pharmacies to include a Pharmacy Customer Bill of Rights for Language Services on their websites.
   - Require pharmacies to engage in broader outreach to inform LEP consumers of their rights to language assistance services and the availability of such services.

(3) Mail Order Pharmacies
Commit to an accelerated study and review of existing systems and processes in place at mail order pharmacies, including efforts already underway to improve language services delivery. Provide meaningful inclusion of the perspective of LEP consumers and patients in any study that is conducted.

(4) Liability
- Institute a plan to monitor covered pharmacies’ compliance with the law.

(5) Waiver
- Eliminate the waiver option. Consult with the Office of Civil Rights for Region II of the US Department of Health and Human Services (HHS OCR) as well as the Federal Coordination and Compliance Section of the Department of Justice (DOJ) to ensure that state policies and procedures comply with federal law.

(6) Standardization
- Include some of the United States Pharmacopeial standards as a starting point to create more comprehensive label standardization regulations. Include input of consumer groups, advocates for special populations, pharmacists, physicians, other health care professionals, and other key stakeholders.

(7) Prescription Pads
- Require that a box be added to the official paper prescription pad similar to the current dispense as written (DAW) box that a prescriber can initial or check if a patient is LEP. Similarly require a check box for prescribers using electronic prescription forms.
- Add a line immediately adjacent to this box for the prescriber to write in the patient’s preferred language, or use a drop-down menu for prescribers using electronic prescription forms.

Incorporating the recommendations in this report will ensure that the SafeRx regulations operate as intended, where millions of consumers in New York have access to patient-centered medication instructions and language assistance services.
I. Overview

SafeRx is designed to ensure maximum access to language assistance services in pharmacies for those who have difficulty using prescription medications safely and effectively due to language barriers, disability, or age-related cognitive and visual impairments. SafeRx is incorporated into New York State law as amendments to the Education Law and the Public Health Law and includes the following provisions:

**Prescription Pads:** Requires regulations to modify prescription forms and electronic prescriptions so that they include a section where a prescriber may indicate if a patient is LEP and the patient’s preferred language. The prescription will not be invalid if this section on the form is not filled out.

**Interpretation and Translation:** Requires covered pharmacies to provide free, competent oral interpretation services and translation services to LEP individuals in that customer’s preferred pharmacy primary language. The translation may occur in a separate document that accompanies the LEP individual’s medication.

**Covered Pharmacy:** Defines a ‘covered pharmacy’ as any pharmacy that is part of a group of eight or more pharmacies, located within New York State and owned by the same corporate entity. A corporate entity shall include related subsidiaries, affiliates, successors, or assignees doing business as or operating under a common trading symbol.

**Pharmacy Primary Language:** Defines ‘pharmacy primary languages’ as those languages spoken by 1% or more of the population, as determined by the US Census, for each region. Regions are to be established by regulation. Covered pharmacies are not required to provide translation or interpretation of more than seven languages in any region.

**Mail Order Pharmacy:** Requires mail order pharmacies to provide free, competent oral interpretation services and translation services to LEP individuals, but first, a study must be conducted to determine how to implement this provision of the law.

**Notification:** Requires covered pharmacies to post notification of translation and interpretation services, with the size, style and placement of the notice to be determined by regulations.

**Liability:** Prevents covered pharmacies from liability for injuries resulting from the actions of third party contractors hired to provide language services as long as the pharmacy entered into the contract reasonably and in good faith and was not negligent.

**Waiver:** Calls for regulations to establish a process that allows covered pharmacies to apply for a waiver from compliance with offering language services.
**Standardization:** Requires regulations to develop standardized patient-centered data elements on prescription labels consistent with existing technology and equipment.

**Local Law:** Permits stronger language access requirements in cities with a population of 100,000 or more.

**II. Frequently Asked Questions**

- **This section provides answers to key questions about why and how SafeRx applies to pharmacies.**

1. **Why Focus on Pharmacies? Are Other Providers Required to Provide Language Assistance Services?**

   While SafeRx focuses on pharmacies, other providers, like hospitals, are required to provide language assistance services. Title VI of the Civil Rights Act requires recipients of federal funding (including Medicaid and Medicare payments) to provide language assistance services for LEP individuals who may require them. Such federal language access requirements have actually been around since the 1960s, but research has shown that pharmacies are less likely to provide the necessary and legally mandated language assistance services than hospitals, even though they frequently encounter LEP customers.

   Standards that guide providers have also been in existence, but pharmacies have not been up to speed in using these standards when compared with other providers. The National Standards on Culturally and Linguistically Appropriate Services (CLAS), for example, are directed at health care organizations and individual providers. Several of these standards are current federal requirements for all recipients of federal funds and the other standards are CLAS guidelines recommended by the Office of Mental Health for adoption as mandates by federal, state and national accreditation agencies. Now, with the enactment of SafeRx, pharmacies similarly have guidance on how to comply with their federal obligation to provide language services. This is critical since pharmacists cannot simply refuse to fill a prescription based on language, as this would constitute discrimination.

2. **Which Pharmacies Must Provide Language Services?**

   SafeRx defines which pharmacies fall under the definition of a “covered pharmacy” and therefore must provide language assistance services. Under SafeRx, a covered pharmacy is defined as “any pharmacy that is part of a group of eight or more pharmacies, located within New York State and owned by the same corporate entity.” A “corporate entity” is defined as including “related subsidiaries, affiliates, successors, or assignees doing business as or operating
under a common name or trading symbol.” The definition of a corporate entity reflects the
notion that while pharmacies throughout New York State may be subject to different corporate
structures—which change over time given the nature of mergers, acquisitions, consolidation,
sale of stock and other corporate decisions—this should not serve as a bar to providing
language services or a reason for pharmacies to escape their federal obligations.

3. **Is it Possible to Provide Competent Language Assistance Services?**

   **(a) Provision of Competent, Quality Language Assistance Services**

   Contrary to requiring haphazard, anything-will-do language services, SafeRx requires *competent, quality* language assistance services. The importance of competent language assistance services is well established in the medical literature and SafeRx is directly responsive to this prevailing consensus. Individuals who are LEP face significant harm when they take medications improperly or do not take them at all due to a lack of access to quality language assistance services. Therefore, a pharmacy cannot simply use Google Translate or request that a child accompanying an adult provide interpretation or translation services to meet their language assistance obligations, both of which likely lead to patient misunderstanding of medication information. Instead, SafeRx provides pharmacies with the flexibility to conduct their own due diligence, but still requires that they provide competent services.

   **(b) The Technology to Provide Language Assistance Services Exists**

   To facilitate the provision of competent, quality language assistance, there is technology that exists and continues to expand in growing recognition of the importance of language services. Numerous telephone services that provide interpretation support for pharmacists who are not bilingual and want to counsel patients in a language they can understand are available. Also, a number of label translation companies that focus on language in the medical context exist that provide high-quality translation medication labels.

   Companies such as RxTran, a label translation company, and Meducation, a linguistically competent patient education tool for pharmacies, emerged in response to the growing need and demand that has resulted from improved enforcement of language access requirements at the state and local level. RxTran, for example, provides translations in 25 languages and utilizes a thorough quality control process to reduce the chance of error. Its protocol requires that three experts review all content that is translated and submitted to the client, and they also must be professional translators, native speakers of the target language, and have a science degree and experience in the appropriate industry. RxTran even provides translation of FDA-approved Medication Guides, which can be downloaded instantly when needed.
Likewise, Meducation provides translation in 11 languages and provides this information at a 5\textsuperscript{th}-6\textsuperscript{th} grade reading level in consideration of patients with low health literacy. Additionally, Meducation uses a double verification method where its translations are done by a qualified medical translation agency and then further verified by a second independent medical translation agency. This should not be read as a specific endorsement of one service over another, and instead should be seen as examples of companies that exist to provide competent language assistance services in the medical context. These kinds of services also help address the concerns that pharmacy personnel may have regarding incorrect translations, since these service providers specifically focus on medical and scientific translation.

Additionally, the National Health Law Program (NHeLP) has published a Language Services Resource Guide for Pharmacists that includes a comprehensive listing of language services providers nationwide and tools for pharmacies to use in evaluating and selecting high-quality, competent providers.\textsuperscript{9} Moreover, since the publication of this document, a national certification process for health care interpreters has been established, allowing for further quality control in the field.\textsuperscript{10} These resources provide pharmacies with the flexibility needed to meet their consumers’ language assistance needs in a competent manner.
Part Two: SafeRx Recommendations

This section discusses specific recommendations surrounding the development of regulations that are required before SafeRx is fully implemented. Under SafeRx, the Commissioner of the State Education Department (SED), in consultation with the Commissioner of Health is required to develop regulations. However, as the body responsible for advising and assisting the SED with pharmacy regulation, the New York State Board of Pharmacy (SBOP) is responsible for developing a draft of SafeRx regulations before final approval from SED. As a result, these recommendations are primarily addressed to the SBOP. The SBOP is a body that consists of pharmacy industry personnel, and does not include consumer or advocate representatives. This lack of other stakeholders underscores the importance of providing recommendations that help protect the interests of those who stand to be most affected by SafeRx regulations developed by SBOP and approved by SED. Therefore, our recommendations reflect best industry practices and serve as a straightforward means of ensuring maximum access to language assistance services for those who are LEP, elderly and who otherwise have low health literacy.

I. Pharmacy Primary Languages:

SafeRx calls for regulations that define regions where language assistance will be provided in those languages spoken by 1% or more of the population. However, the SafeRx regulations defining regions must balance maximal inclusion of the many diverse populations of New York State with ease of administration for covered pharmacies. Determining the pharmacy primary languages should be accomplished through applying a uniform state standard where covered pharmacies provide language assistance services in the top 6 or 7 non-English languages across the state. While the law currently ensures that pharmacies are not required to provide the services in more than 7 languages, using a straightforward approach where all pharmacies provide the same 6 or 7 non-English languages would be most effective because it encourages consistency. Therefore, we recommend that the SBOP:

1. Use a straightforward approach that requires translation in the top 6 or 7 non-English languages spoken throughout the state. This falls in line with the approach taken in other instances where language assistance was provided.

In 2008 for example, the New York State Office of the Attorney General (OAG), prompted by consumer complaints, investigated and reached settlement agreements with seven of the top chain pharmacies operating in New York State to improve their language assistance services
after finding that they failed to provide such services. Pursuant to those settlement agreements [an example is attached as Appendix A], those chain pharmacies were required to provide translations in the top six languages spoken in New York, with five additional languages to be added over time based on the pharmacies’ internal data collection. A similar approach was taken for the New York City Language Access in Pharmacies Act. Notably, almost 90% of LEP individuals in New York State speak one of the top seven non-English languages,\(^{13}\) ensuring that the vast majority would be able to access services if this approach is taken. Further, a “top 7” approach is also administratively straightforward for pharmacies themselves, which can roll out a single system of language services delivery across their company, rather than modifying their services for smaller regions or localities.

There is no reason to “recreate the wheel” and develop a new system for determining pharmacy primary languages. Existing approaches are already in place and are working effectively. The OAG, for example, continues to monitor the compliance of the pharmacies that entered settlement agreements, finding that these pharmacies’ provision of language assistance in the top languages has not posed major problems.\(^{14}\) A change may only foster disruption, impose unnecessary costs, and lead to consumer confusion. Additionally, this straightforward approach reflects the position advocated by the Chain Pharmacy Association of New York State testimony before the Senate Finance Committee and Assembly Ways & Means Committee on February 8, 2012 [an excerpt is attached as Appendix B], whereby a single state standard was recommended. Applying a single state standard such as “top 7 languages” ensures administrative ease, compared to analysis and application of a multitude of regional standards. From there, pharmacies covered under SafeRx have the flexibility needed to determine the best means of providing language assistance services, including how to provide translation, and whether to hire bilingual pharmacists or use a telephone service to interpret medication information. This flexibility and implementation of a top 7 approach create a straightforward means of implementing language assistance services.

Further, while SafeRx does not require covered pharmacies to provide language assistance services in more than seven languages, the law also does not limit the ability of pharmacies to provide language assistance for individuals who speak languages other than the top seven. Indeed, providing interpretation services in any language would be fairly simple to do in instances where a language phone line is used, as the pharmacy will already have arranged provision of services and need only make a phone call and request the language in question.

In the alternative, we recommend that the SBOP apply a common approach taken in other health and critical non-health settings to determine “pharmacy primary languages” and:
2. Use Census and other relevant data to determine the top languages spoken by 1% or more of the limited English proficient ("LEP") population in a given area, rather than 1% of the general population.

This approach ensures that translation services are available to those who actually need them, and that health care providers are not using resources to translate documents into languages spoken by individuals who are also English proficient. The New York State Department of Health hospital language access regulations utilize the 1% of LEP threshold. The relevant “region” or service area for the determination of pharmacy primary languages should be defined broadly enough to cover the communities that require essential services, but with a view toward administrative simplicity.

II. Notification of Rights to Language Services

SafeRx requires promulgation of regulations pertaining to the size, style and placement of notification signs for patients’ rights to language services in pharmacies. Adequate notification is essential to ensure that both patients and pharmacists are reminded of the availability of language assistance services and are encouraged to use the services. We recommend that the SBOP implement best practices with respect to notification, including conspicuous placement of notification at pharmacy entrances and pharmacy counters. We further recommend:

1. Use of a standard message regarding patients’ rights and translation of that message in multiple languages. For example, the US Census Bureau publishes a set of “I Speak” flashcards, which repeat the same message in multiple languages.

LEP individuals can point to the language they speak to signal to a service provider that they need interpretation and translation services in that language [Please see a sample attached as Appendix C]. In addition, in implementing the New York State Financial Assistance Law, the Department of Health developed multilingual signs that informed patients in over a dozen languages of their right to financial assistance in hospitals [Please see a sample attached as Appendix D].

In the pharmacy context, such signage has been required under the settlement agreements that the OAG reached with seven major chain pharmacies operating in the state. In addition to requiring multilingual signs to be conspicuously located at or near the pharmacy counter, the settlement agreements required notification of a Pharmacy Customer Bill of Rights for Language Services on the pharmacies’ website as well. The specific language required is as follows:
Pharmacy Customer Bill of Rights for Language Services:

- The right to understand all information necessary to ensure the safe and effective use of prescription medications.
- The right to receive counseling from a pharmacist in the language you speak.
- The right to interpreter services to ensure that communications with a pharmacist can take place in your language.
- The right to have vital documents, such as the directions for use of a prescription drug, translated into your language or explained to you by an interpreter.
- The right to file a complaint with the pharmacy if you do not receive assistance or if any staff member violates these rights.

Therefore, we recommend that the SBOP:

2. Promulgate regulations mandating a similar notification for pharmacies subject to the SafeRx legislation.

Several pharmacies already have such signage in place as a result of settlement agreements, they will face no additional burden and would also have the added advantage of consistency across the board. Pharmacies covered under SafeRx but not covered under the settlement agreements would therefore have a model of signage that can be posted.

In addition to requiring signage, we recommend that the SBOP require pharmacies to engage in broader outreach to inform LEP consumers of their rights to language assistance services and the availability of such services.

Doing so will ensure that LEP consumers use available interpretation and translation services. Potential methods of outreach might include:

- Placement of ads in local media outlets (newspaper, radio, TV, internet). After signing settlement agreements with the New York State Attorney General, Rite-Aid Pharmacy, launched precisely such an ad campaign to signal that they were welcome to and able to serve LEP communities [please see a sample attached as Appendix E].
- Telephone notification regarding the availability of language assistance services. Many patients interact with their pharmacies via telephone, which offers an important opportunity to inform patients of the availability of language assistance services.
- Collaboration with local community-based organizations and other groups that have extensive interaction with LEP individuals. Health plans and other health care
entities often participate in local health fairs and events and conduct outreach to local organizations in order to expand outreach and market share.

III. Mail Order Pharmacies

SafeRx requires mail order pharmacies to provide free, competent oral interpretation and written translation services to individuals filling prescriptions through mail orders, pending the completion of a study and formal rulemaking process developed through regulations.\textsuperscript{18}

Some mail order pharmacies have already been required to evaluate the adequacy and the efficacy of how to deliver language assistance services. In 2005, for example, the U.S. Department of Health and Human Services Office of Civil Rights (HHS OCR) investigated the mail order prescription benefits manager, Medco Health Solutions, Inc. (Medco) in response to a consumer language access complaint.\textsuperscript{19} To resolve the complaint and in recognition of the “business need to address the issue of language assistance services,” Medco provided HHS OCR with written assurances to implement a series of corrective actions [attached as Appendix F], which included:

- The launch of a multi-year “Other Than English Language” project designed to evaluate and improve Medco’s systems, process, policies and procedures for providing language assistance services;
- Expanding the number of Spanish-language bilingual staff and creation of a system to re-route Spanish speaking patients to these bilingual advisors and staff;
- Evaluation of a multilingual, starting with Spanish, “tagline” on Medco documents directing patients’ to a phone assistance line with bilingual staff and/or interpreter services;
- Translation of key Medco written and web communications;
- Assessment of bilingual staff language capabilities; and
- Improvements to Medco’s computer system to enable LEP patients to be “flagged” for language assistance services.\textsuperscript{20}

Medco was also able to make interpretation services available in over 150 languages through a designated phone interpretation contract. The provision of language assistance services, and the mechanisms by which to provide them, is therefore not a new issue for mail order pharmacies. Mail order pharmacies have already begun to explore language access on a national level and the systems that mail orders have in place to ensure language access are also very similar to those required of bricks-and-mortar pharmacies.

In light of this background, we recommend that the SBOP:
1. Commit to an accelerated study and review of existing systems and processes in place at mail order pharmacies, including efforts already underway to improve language services delivery.

Given the strides that have already been made in understanding how language services are utilized and delivered in the mail order context, as evidenced by the Medco OCR agreement, the state need not spend a full year conducting a study before promulgating regulations. We additionally recommend:

2. Meaningful inclusion of the perspective of LEP consumers and patients in any study that is conducted.

In the Medco case described above, the company canceled a prescription refill for a patient with a chronic medical condition when he failed to respond to requests for action provided to him in English only. This is but one example of the threats to health that can occur when mail order pharmacies do not abide by federal obligations to provide language assistance. The harm caused when pharmacies fail to provide language assistance services is grave and extends to consumers who use mail orders to fill their prescriptions. Such consumers can speak about the details of the problems that are caused when mail orders do not provide language assistance. Therefore, including consumer voices in the study conducted by the state pursuant to SafeRx will be essential in ensuring that such harms are significantly reduced and that services are designed in a manner that promotes equal and safe access.

As is the case with retail pharmacies, mail orders are bound not only by existing local and state law but also by federal civil rights mandates that represent a floor for the standards of language assistance provision nationwide. Put simply, the state cannot require less of mail order pharmacies operating in New York than would be required of them nationally. Any study conducted by the state must therefore also include an analysis of existing legal requirements and best practices. Many resources exist that can facilitate such an analysis.

IV. No Liability for the Actions of Third Parties

Under SafeRx, covered pharmacies are held harmless for liabilities stemming from the actions of third parties. We understand the concern about pharmacy liability and the desire to ensure that covered pharmacies are not penalized for the injuries that may result from the actions of third party contractors. To help prevent liability, we recommend that the SBOP:

1. Institute a plan to monitor covered pharmacies’ compliance with the law, as we believe that this will be beneficial both to the covered pharmacies as well as the population served.
To facilitate covered pharmacies’ compliance with the legislation, monitoring can be of great use because it allows a body with expertise to provide specific input and feedback about a covered pharmacy’s compliance with the law. Pharmacies have and can be held liable for failing to provide language assistance services. Thus, monitoring may help circumvent the types of complaints that led to the OAG investigation discussed above. In that investigation, the OAG found that seven chain pharmacies across the state had failed to provide language assistance services and reached settlement agreements with those pharmacies. After these agreements were reached, a statewide survey of pharmacies’ compliance with the settlement agreements was conducted in 2010, and found significant improvements in the provision of language services. Monitoring helps protect both the covered pharmacy and the consumer by providing the guidance needed to prevent the liability that may result from a pharmacy’s failure to provide appropriate translation and interpretation services, and it provides consumers with access to better services.

V. **Ability to Seek a Waiver**

Under SafeRx, covered pharmacies may seek a waiver from providing the language assistance services. However, the waiver provision is incredibly troubling. First, the intent of SafeRx is to define and make clear which pharmacies have a federal obligation to provide language assistance. Second, since SafeRx sufficiently defines the appropriate pharmacies that have a federal obligation, a waiver would permit a pharmacy to be noncompliant with federal law. Third, a waiver eliminates the consumer’s voice on whether or not services should be provided. Therefore, we strongly recommend that the SBOP:

1. **Eliminate the waiver option.** The definition of a covered pharmacy does not include independent pharmacies, or small “mom & pop” pharmacies. SafeRx only captures large pharmacies that generate millions of dollars in pharmacy revenue.

SafeRx operates above a floor of federal civil rights law, which mandates that all recipients of federal financial assistance, including Medicaid and Medicare reimbursements, provide access to their customers without discrimination on the basis of race or national origin. The U.S. Supreme Court has determined that failure to provide language assistance services constitutes discrimination on the basis of national origin. Chain and mail order pharmacies, described as “covered pharmacies” under the legislation, fall clearly within the purview of these federal civil rights requirements, as they receive substantial Medicaid and Medicare payments through their patients. As such, the pharmacies covered under SafeRx are required by federal law to provide language assistance and may not be exempt from providing these services under state law given the requirement to counsel patients.
Several of the “covered pharmacies” are subject to settlement agreements with the OAG that are predicated on their compliance with federal law and require significant improvements in the pharmacies’ provision of language assistance services. As discussed above, Medco is subject to a similar agreement with HHS OCR. Given the longstanding and overriding role of federal civil rights law in this area, any regulations promulgated to implement the SafeRx legislation must seek to foster compliance with existing federal mandates, and not undermine them. Thus, it would be inappropriate for a covered pharmacy to seek a waiver from its federal obligation.

In the event that the SBOP decides to provide a waiver process—that conflicts with federal law—such a waiver must only be permitted in the most limited of circumstances. Waivers must be extraordinarily rare and only applied where a covered pharmacy has demonstrated every effort to comply with its obligation to provide language assistance. As seen in the example of the OAG settlement agreements, a weak waiver process can trigger state and federal investigation of covered pharmacies. Therefore, we recommend:

2. Consultation with the Office of Civil Rights for Region II of the US Department of Health and Human Services (HHS OCR) as well as the Federal Coordination and Compliance Section of the Department of Justice to ensure that state policies and procedures do not themselves run afoul of federal law.

The U.S. Department of Justice (DOJ) has published Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons [attached as Appendix G]. In this guidance document, the DOJ established a four-factor language assistance test requiring recipients of federal funding to take reasonable steps to ensure meaningful access to its services by LEP individuals and compliance with federal law. These four factors include review of (1) the number of LEP individuals served by the program; (2) the frequency with which LEP individuals come in contact with the program; (3) the nature and importance of the program; and (4) the resources available to implement the services. Given that covered pharmacies are not exempt from providing language services under federal law, and must take a number of precautions to comply with federal law, there should not be exemptions made available under state law.

Providing language assistance services improves delivery of healthcare and increases efficiency of distribution of government services to LEP individuals, consequently decreasing the need for long-term and more costly services to the State and to society. Thus, we strongly recommend that a covered pharmacy not be permitted to waive the SafeRx requirements and that HHS OCR or DOJ be consulted to help ensure that there is no violation of federal law.
VI. Standardization

We appreciate the requirement calling for development of rules and regulations regarding standardized patient-centered data elements on prescription drug labels. There is significant medical literacy research that discusses the problems that consumers have faced in attempts to understand medication prescription labels, which are often complicated and difficult to understand. As an initial matter, nearly half of all adults in the U.S. lack the skills needed to understand health information including instructions on medication levels, and for those who take multiple medications, who have low health literacy, and who are LEP, the risk of misunderstanding medication instructions is significantly higher.

Several factors contribute to patient misunderstanding of medication labels. In addition to language barriers, research has shown that even in English, the medication information provided on prescription labels is presented in a confusing manner that increases likelihood of medication errors. For example, some medication instructions fail to provide critical information such as explicit dose frequency or precise timing of medication administration. Further, some prescription labels lack warnings regarding potential adverse effects altogether. Even when warnings are included, consumers often have difficulty understanding them because of word choice, message length, compound sentences requiring multiple steps, confusing icons, and use of misleading colors where text highlighted in certain colors is mistaken as a suggestion rather than an actual warning. Research has even shown that patients become confused when the largest item on a label is the pharmacy logo, and other components such as medication instructions and warnings are considerably smaller in font size.

Significant research has been conducted on the steps that can be taken to make prescription labels more patient-friendly and reduce medication errors. Standardization of signatura (sig) messages—drug label dosage instructions—is a process that can help improve readability and help reduce medication errors. Standardization of medication instructions will help reduce the problems associated with labeling because it incorporates evidence based techniques that have been shown to improve prescription readability and understanding.

To aid in the creation of standardized, patient-friendly labels, the U.S. Pharmacopeial Convention (USP) is developing a new national standard for prescription labeling. The USP is the nonprofit scientific organization that sets FDA-enforceable standards for the quality, purity and strength of medicines in the United States. We recommend that the SBOP:

1. Include the following USP standards as a starting point to create more comprehensive label standardization regulations. We anticipate robust inclusion of consumer groups, advocates for special populations, pharmacists, physicians, other health care professionals, and other key stakeholders as called for in SafeRx.
(a) Organize the prescription label in a patient centered manner

This standard calls for organizing prescription label information in a way that best reflects how most patients understand medication instructions, featuring the most important information for safe and effective understanding and use. For example, the layout should present information in order of importance and should include information such as the name of the medication, instructions for use, contraindications, precautions and warnings, how the medication works, side effects, contacts for emergencies and additional information sources. Further, such information should be presented in a way that is based on well-known cognitive principles such as:42

- Information load (amount of information presented)
- Study time (the amount of time someone will actually spend reading the information)
- Chunking (breaking items up into smaller pieces of information)
- Depth of processing (the way information can be processed to increase memory)
- Linguistic coding (naming or coding information)
- Use of prior knowledge (knowledge from previous experiences that make it easier to learn and recall new information).

(b) Emphasize instructions and other important information to patients

This component of standardization calls for prominently displaying information that is critical to a patient’s safe and effective use of the medicine, including the patient’s name, drug name and strength, and clear directions for use. Less critical information such as the pharmacy name and number should not supersede critical patient information.

(c) Simplify language

Building on the cognitive principles listed above, language on the label should be clear, simplified, concise and familiar. Unfamiliar words such as Latin terms and unclear medical jargon should not be used. Translation of sigs, or drug label dosage instructions, should also be used to further clarify the information presented.

(d) Give explicit instructions

Instructions should clearly separate the dose itself from the timing of each dose and use numeric characters. For example, saying “take 2 tablets in the morning and 2 tablets in the evening” rather than “take two tablets twice daily,” more clearly distinguishes the timing for taking each dose. A universal medication schedule (UMS) may be used to assist with this as
well, as this schedule includes four standard times for dispensing of medication: morning, noon, evening, and bedtime. This schedule, which accounts for nearly 90% of how medications in pill form are prescribed, can help eliminate the confusion surrounding when to take medication and simplifies labeling instructions.

(e) Improve readability

The label type should use the following to ensure optimal readability:

- High-contrast print such as black print on white background
- Large font size (e.g., minimum 12-point Times New Roman or 11-point Arial)
- Horizontal text only
- Adequate white space between lines of text (e.g., 25% to 30% of the point size, or double-spacing), especially to distinguish sections on the label
- Highlighting, bolding, and other cues that emphasize patient-centric information

(f) Limit auxiliary information

Labels, stickers, or other supplemental information should be expressed in simple and explicit language that is minimized to avoid distracting patients with nonessential information. This includes limiting use of pictographic icons, which are frequently misunderstood by patients, and which can be ineffective at improving understanding compared with simplified text alone. At best, the effectiveness of icons is inconclusive and there is not enough evidence sufficient to support exclusive use of pictographic icons. When considering cultural diversity, linguistic diversity, and diversity of age, and how these factors impact the way in which one interprets a pictograph, it is not difficult to understand how using pictographic icons without clear, concise written instruction can be confusing for patients and misunderstood, rather than helpful.

(g) Include accommodations to address special populations

By adopting standardized labeling, special populations such as those who are limited English proficient, the elderly, children and their caretakers, those with disabilities, and those who otherwise have low health literacy and have trouble understanding medication instructions, will be better equipped to understand prescription medication instructions. Consumers and advocates for these special populations must be included in the process to develop patient-centered labeling, as they are most equipped to provide guidance on other areas of concern with labeling and can provide solutions to address these problems.
VII. **Promoting Language Accessibility on New York State Prescription Pads**

SafeRx requires the Department of Health (DOH) to promulgate regulations modifying the official paper and electronic New York State prescription pad so that a prescriber may indicate (1) if a patient is LEP and, if so, (2) the patient’s preferred language. The modification of the official prescription pad will not only provide a signal to pharmacies to ensure that language assistance is made available, but it will also serve as a check for the prescriber to ensure that he or she too is providing the necessary services.

To update the prescription pad format, we recommend that the DOH:

1. Require that a box be added to the official paper prescription pad similar to the current dispense as written (DAW) box that a prescriber can initial or check if a patient is LEP.

2. Add a line immediately adjacent to this box for the prescriber to write in the patient’s preferred language. Such a design will consume minimal space on the existing prescription pad form, while also ensuring that the information required by law is sufficiently included.

For electronic prescriptions (prescription forms filled in online), which offer more flexibility, we recommend that the DOH:

3. Require a check box for prescribers to indicate if a patient is LEP.

4. Use a drop-down menu or similar structure for the prescriber to indicate the patient’s preferred language. Existing pharmacy language assistance software, such as Meducation and RxTran, already contain this drop-down feature.

- **When you can’t understand your prescription, it might as well be BLANK**
Conclusion

Patient advocates and pharmacy researchers agree that language barriers and information inconsistencies are the root causes of patients’ confusion over how to take prescription medications properly. As a result of these barriers and inconsistencies, seniors and LEP individuals put their lives in danger at many chain pharmacies around the State. Therefore, implementing the SafeRx recommendations discussed in this report is essential to ensuring that New York’s increasingly diverse communities have equal and safe access to prescription medications.

Our Organizations

Make the Road New York
Make the Road New York is a membership-led organization. MRNY builds the power of Latino and working class communities to achieve dignity and justice through organizing, policy innovation, transformative education, and survival services. MRNY’s multi-faceted approach includes organizing and activism, collaborative learning and a community of support to provide badly needed services to members and leaders.

Center for Popular Democracy
The Center for Popular Democracy (CPD) promotes equity, opportunity, and a dynamic democracy in partnership with the most innovative community-based organizations, local and state networks, and progressive unions across the country. CPD works to develop cutting-edge state & local policies that deliver tangible benefits to communities; and build organizational infrastructure & capacity so our partners can grow stronger and expand.

New York Lawyers for the Public Interest
New York Lawyers for the Public Interest (NYLPI) is a nonprofit, civil rights law firm that advances equality and civil rights through the power of community lawyering and partnerships with the private bar. NYLPI’s Health Justice Program partners with community-based groups throughout New York to remedy systemic barriers to health care access through administrative enforcement of civil rights laws, litigation, legislative drafting, lobbying and other forms of advocacy.
Endnotes

1. Interpretation is when a person comprehends a spoken message and re-expresses that message accurately in another language. Translation is the conversion of a written text from one language into an equivalent written text in another language.
7. N.Y. EDUC. LAW § 6829(1)[A] (2012).
12. These pharmacies are CVS, Rite-Aid, Walmart, Duane Reade, A&P, Costco and Target.
13. These languages are Spanish, Chinese, Russian, Italian, Korean, French Creole and Yiddish. U.S. Census Bureau, 2008-2010 American Community Survey.
14. Please contact the OAG for additional information.
15. 10 N.Y.C.R.R. § 405.7.
20. Letter from Michael Carter, Regional Manager for US Department of Health and Human Services Office of Civil Rights Region II to David B. Snow, Chairman of the Board and Chief Executive Officer of Medco Health Solutions, Inc. (May 28, 2009), attached as Appendix H.
21. See Part One, Section II(3).
27. U.S. Dep’t of Health and Human Services, supra note 19.
29. For any dataset used to determine a number, the margin of error, changes in the population and confounding variables that may impact the dataset must be considered.
30. Consultation with HHS OCR or DOJ is critical here because it is not sufficient to rely only on past-usage data alone.
Gulker, Max, “The Benefits and Costs of Pharmacy Translation and Interpretation Services Under SafeRx Legislation,” NERA Economic Consulting, Mar. 9, 2012, at 2. According to this research, the estimated cost to covered pharmacies of providing interpretation and translation amounts to approximately 0.03% (one three-thousandth) of the pharmacies’ annual revenue from prescription drug sales in New York. This cost is minimal and “highly unlikely” to materially affect the operations of covered pharmacies.


N.Y. EDUC. LAW §6830 (2012).


See Wolf, Michael S. et al., supra note 34 at 4.

Shrank, William S. et al., supra note 34 at 1762-63.


Shrank, William S. et al., supra note 34 at 1761-62.

Wolf, Michael S. et al., supra note 34 at 2.


Wolf, Michael S., “Effect of Standardized, Patient-Centered Label Instructions to Improve Comprehension of Prescription Drug Use,” Medical Care, Jan. 2011; 49(1); 96-100.


N.Y. PUB. HEALTH LAW §21(2) (2012).

For a discussion of available language assistance technology, see Part One, Section II(3).
APPENDIX A
ATTORNEY GENERAL OF THE STATE OF NEW YORK
CIVIL RIGHTS BUREAU

ASSURANCE OF DISCONTINUANCE
PURSUANT TO EXECUTIVE LAW
SECTION 63(15)

In the Matter of: ASSURANCE OF DISCONTINUANCE
PURSUANT TO EXECUTIVE LAW
SECTION 63(15)

WHEREAS, Andrew M. Cuomo, the Attorney General for the State of New York
("OAG"), has made an inquiry pursuant to the provisions of Section 63(12) of the Executive Law,
into the policies, procedures and practices of CVS Pharmacy, Inc. ("CVS") regarding its provision
of language assistance services to pharmacy customers with limited English proficiency ("LEP");

WHEREAS, CVS is a Rhode Island corporation having its corporate offices at One CVS
Drive, Woonsocket, RI 02895;

WHEREAS, CVS owns and operates approximately 428 pharmacies located in New York
State, which pharmacies are registered pursuant to 8 N.Y.C.R.R. Part 63;

WHEREAS, pharmacists employed by CVS are required pursuant to 8 N.Y.C.R.R. §
63.6(b)(8) to personally counsel each patient (or patient representative) in matters which the
pharmacist deems appropriate, such as the name of the medication, the dosage, route of delivery,
and duration of therapy, precautions for preparation, common side effects or adverse effects,
contraindications, and storage, unless such counseling is refused;

WHEREAS, pharmacists employed by CVS are required pursuant to 8 N.Y.C.R.R. §
63.6(b)(7) to solicit from patients the information they need to fully counsel those patients about
the safe and effective use of prescription medications. This information includes, among other
things, known allergies and drug reactions, chronic diseases, and a comprehensive list of
medications taken by the patient;

WHEREAS, pharmacists employed by CVS are required pursuant to N.Y. Educ. Law §
6810(1) to affix labels to all prescription medications that they dispense, which labels must
include, among other things, the directions for use of the drug by the patient as given upon the
prescription;

WHEREAS, the words, statements or other information to be printed on a prescription
medication label must be in such terms as to render it likely to be read and understood by the
ordinary individual under customary conditions of purchase and use, pursuant to N.Y. Educ. Law
§ 6815(2)(c);

WHEREAS, New York State Civil Rights Law §40-c provides that no person shall,
because of race, creed, color, national origin be subjected to any discrimination in his or her civil
IT NOW APPEARING THAT CVS desires to settle and resolve the Investigation without admitting or denying the OAG’s findings, the OAG and CVS hereby enter into this Assurance of Discontinuance.

I. DEFINITIONS

1.1 “Agreement” means this Assurance of Discontinuance.

1.2 “CVS” means CVS Pharmacy, Inc., a corporation formed under the laws of Rhode Island, and any of its predecessors, successors, members, subsidiaries, or assigns.

1.3 “Pharmacy” means any place in which drugs, prescriptions or poisons are possessed for the purpose of compounding, preserving, dispensing or retailing, or in which drugs, prescriptions or poisons are compounded, preserved, dispensed or retailed, or in which such drugs, prescriptions or poisons are by advertising or otherwise offered for sale at retail.

1.4 New York Store” means all CVS stores located in New York State and registered to operate a pharmacy under 8 N.Y.C.R.R. Part 63.

1.5 “Employee” means any person performing work for and compensated by CVS.
1.6 "Pharmacy Staff” means any Employee who works in the Pharmacy of a New York Store.

1.7 "Pharmacy Services” mean any services relating to prescription medications.

1.8 “Customer” means any person seeking services from the Pharmacy of a New York Store, or the authorized representative of such person.

1.9 “LEP Customer” means a Customer whose primary language is not English and who cannot speak, read, write, or understand English at a level sufficient to permit such Customer to communicate in English about the safe and effective administration of prescription medications, or otherwise communicate effectively with Pharmacy Staff.

1.10 “Customer’s Primary Language” means the language primarily spoken by an LEP Customer and in which such Customer requires language assistance.

1.11 “Prescription Drug Information” means any information pertaining to the safe and effective use of a prescription drug, including but not limited to the dosage, route of delivery, duration of therapy, precautions for preparation, common side effects or adverse effects, contraindications, and storage.

1.12 “Counseling” means the communication by a pharmacist or pharmacy intern to a Customer of information relating to the safe and effective use of a prescription drug, which information may include: (1) the name and description of the medication and known indications; (2) dosage form, dosage, route of administration and duration of drug therapy; (3) special directions and precautions for preparation, administration and use by the patient; (4) common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur; (5) techniques for self-monitoring drug therapy; (6) proper storage; (7) prescription refill information; and (8) action to be taken in the event of a missed dose.

1.13 “Medication Profile” means information relating to a Pharmacy Customer including, but not limited to, the Customer’s name, address, telephone number, gender, date of birth or age, known allergies and drug reactions, chronic diseases, a comprehensive list of medications and relevant devices and other information reported to the pharmacist appropriate for counseling an individual regarding use of prescription and over-the-counter drugs.

1.14 “CVS Written Languages” shall include English, Spanish, Chinese, Italian, Russian and French. CVS shall add five additional languages to the CVS Written Languages within six months after full implementation of its new pharmacy computer system (“CVS Pharmacy Computer System”). The full implementation of the CVS Pharmacy Computer System shall take place by March 31, 2010. CVS shall notify the OAG of the date of full implementation, within 30 days of occurrence. CVS shall choose the five additional
languages based on an assessment of the Primary Languages of the greatest number or highest proportion of LEP Customers eligible to be served or likely to be encountered by the Pharmacies of the New York Stores.

1.15 "Effective Date" means the date this Agreement is executed by the parties hereto.

II. ATTORNEY GENERAL'S INVESTIGATION AND FINDINGS

2.1 The OAG received complaints from numerous LEP Customers who had filled prescriptions at a variety of CVS stores. The complainants alleged that CVS repeatedly failed to provide them with adequate interpretation and translation services. Specifically, they alleged that CVS did not provide them with prescription drug labels printed in their Primary Language, so they were unable to read and understand the instructions for use. The complainants also alleged that CVS did not offer or provide them with prescription drug counseling in their Primary Language.

2.2 The OAG commenced an investigation into CVS' policies, procedures, and practices regarding language assistance services for LEP Customers. The investigation consisted of undercover contacts with CVS Pharmacies in which investigators sought assistance in languages other than English, and a thorough review of CVS documents.

2.3 The OAG investigation found that, although CVS had taken some steps to ensure equal access to pharmacy services for LEP Customers, including building capacity to print prescription drug labels and other vital documents in Spanish and contracting with a telephonic interpreter service:

a. CVS had not conducted an analysis of the language assistance needs of the communities it serves;

b. CVS did not provide sufficient training to its Pharmacy Staff concerning their legal obligation to make services accessible to LEP Customers;

c. CVS did not provide adequate notice to its Customers who needed language assistance how CVS could provide those Customers equal access to its Pharmacy Services;

d. CVS did not consistently offer or provide language-appropriate Counseling to LEP Customers; and

e. CVS did not have the capacity to print prescription drug labels or the instructions for use of a prescription drug in any language other than English or Spanish, and did not consistently print such labels or instructions in any language other than
English.

Based on the foregoing, the OAG has determined that failure to provide adequate language assistance services for prescription medication is unlawful. CVS offers this Assurance of Discontinuance in settlement of the violations alleged by the OAG, and the OAG accepts the specific assurances made herein pursuant to Section 63(15) of the New York Executive Law in lieu of commencing a civil action. CVS asserts that this Assurance of Discontinuance is in no regard an admission of guilt or liability by CVS regarding the allegations set forth above.

III.
COMPLIANCE WITH LAW

3.1 CVS shall comply fully with the obligations, terms and conditions set forth in Title VI and the regulations promulgated thereunder, the New York Human Rights Law, the New York City Human Rights Law, the New York Civil Rights Law, the New York Education Law and the regulations promulgated thereunder.

IV.
PROVISION OF EQUAL ACCESS TO PHARMACY SERVICES

4.1 Pharmacy Customer Bill of Rights for Language Services

CVS shall adopt and abide by the Pharmacy Customer Bill of Rights for Language Services, attached hereto as Exhibit A, and shall post such Bill of Rights in English and CVS' Written languages on CVS' website. Nothing in this paragraph or in CVS' adherence to the Customer Bill of Rights shall in any way affect or limit CVS' obligations under this Assurance of Discontinuance.

4.2 Equal Access to Pharmacy Services

CVS shall ensure equal access to pharmacy services for its Customers, regardless of national origin, by providing language assistance to those Customers who require such assistance to communicate with Pharmacy Staff and to receive services related to prescription medications.

4.3 Written Language Assistance Policy

Within 30 days of the Effective Date, CVS shall create a written policy ("Language Assistance Policy"), subject to the approval of the OAG, describing the language assistance procedures designed by CVS to ensure equal access to pharmacy services as required by this Agreement.
4.4 Notice to Customers of their Right to Language Assistance

Within 30 days of the Effective Date, CVS shall inform Customers of their right to free language assistance services. Multilingual signs advising Customers of the availability of free language assistance services shall be posted in conspicuous places in the Pharmacies of all New York Stores and on CVS’ website.

4.5 Language Assistance Services

Pharmacy Staff shall communicate with Customers in each Customer’s Primary Language when: 1) soliciting information necessary to maintain a patient medication profile; 2) offering prescription drug counseling; 3) providing prescription drug counseling, where such counseling is not refused by the Customer; 4) accepting in-person and telephonic prescription drug refill requests; and 5) when otherwise necessary to ensure the safe and effective use of prescription drugs. CVS shall ensure such information is communicated, at no extra charge, to Customers in each Customer’s Primary Language, for in-store and over-the-telephone assistance, by using the free interpretation resources set forth below.

a. Telephonic Services

In store and customer call-in communications: CVS shall continue to maintain a contract with a provider of telephonic interpretation services to provide immediate, simultaneous interpretation of communications between LEP Customers and Pharmacy Staff. The telephonic interpretation service shall have available trained interpreters who speak all of the languages that CVS can reasonably expect its LEP Customers to speak and shall be accessible to all Pharmacy Staff during Pharmacy business hours. Pharmacy Staff shall access the service as necessary to ensure verbal communications between Pharmacy Staff and LEP Customers take place in the Customer’s Primary Language. In order to ensure proper provision of simultaneous interpretation services, the Pharmacy shall be equipped with either dual-handset telephone or any other configuration of telephonic equipment to allow for simultaneous interpretation services. The installation of such telephones shall be completed within 180 days of the Effective Date. Pharmacy Staff training on such equipment shall occur within 15 days of installation and shall be provided by the telephonic interpretation services provider. Such training shall include a procedure distributed to all Pharmacy staff and available at all pharmacies, and field training on how to use the telephone dual-handset or other necessary telephonic equipment.

b. Pharmacy Staff

Effective January 31, 2009, before a Pharmacy Staff person communicates in the usual course of store operations Prescription Drug Information to any LEP Customer (either directly, as in the case of Pharmacists, or in the capacity as interpreter, as in the case of other Pharmacy Staff), CVS shall assess such Pharmacy Staff person’s language abilities
and determine them to be sufficient to communicate Prescription Drug Information effectively in the LEP Customer’s Primary Language. CVS shall contract with a vendor to assist with this assessment. The choice of vendor and assessment tool shall be subject to the approval of the OAG, which shall not be unreasonably withheld. CVS shall maintain data regarding the methodology and assessment of all Pharmacy Staff persons deemed qualified to communicate Prescription Drug Information in languages other than English, and shall incorporate and maintain such assessments in Pharmacy Staff persons’ personnel profiles.

4.6 Translated Documents

CVS shall translate into CVS’ Written Languages all prescription drug label information, warning labels and vital documents as set forth below.

a. Prescription Drug Labels

Within 45 days following the full implementation of the CVS Pharmacy Computer System, which shall occur by March 31, 2010, when filling a prescription for an LEP Customer, CVS shall print the directions for use of the prescription drug in both English and the Customer’s Primary Language if the LEP Customer’s Primary Language is among CVS’ Written Languages. Where the LEP Customer’s Primary Language is not among those languages translated by CVS, CVS shall print the instructions for use in English and shall employ telephonic interpreter resources or Pharmacy Staff as described in paragraph 4.5 to verbally communicate the instructions for use to the Customer in his/her Primary Language.

b. Warning Labels

Within 45 days following CVS’ full implementation of the CVS Pharmacy Computer System, which shall occur by March 31, 2010, when filling a prescription for an LEP Customer, in circumstances where CVS Pharmacy Staff deem it appropriate to affix labels, in addition to and separate from the prescription drug labels referred to in paragraph 4.6.a, with information regarding the safe and effective use of the prescription drug, including but not limited to common side effects or adverse effects and contraindications (“Warning Labels”), CVS Pharmacy Staff shall affix such labels in both English and the Customer’s Primary Language if the Customer’s Primary Language is among CVS’ Written Languages. Where the LEP Customer’s Primary Language is not among those languages translated by CVS, CVS shall affix the Warning Labels in English and shall employ telephonic interpreter resources or Pharmacy Staff as described in paragraph 4.5 to verbally communicate the information conveyed by the Warning Label to the Customer in his/her Primary Language.
c. **Vital Documents**

Within 90 days of the Effective Date, CVS shall translate the following materials into all CVS Written Languages and shall make such translated material available in the same manner as the corresponding English-language documents:

1. notices of privacy practices, as required by 45 C.F.R. § 164.520;
2. written offers of counseling, as required by 8 N.Y.C.R.R. § 63.6(8)(ii)(a); and
3. any other material CVS considers vital to a Customer’s safe and effective use of prescription medications.

4.7 **Training**

CVS shall provide annual training for all Pharmacy Staff regarding CVS’ language assistance policies and procedures as set forth in this Agreement. As part of this training, Pharmacy Staff shall be given copies of CVS’ Language Assistance Policy and the one-page summary of such Policy. CVS shall provide such training to all new Pharmacy Staff within 30 days of their date of hire. All Pharmacy Staff shall sign an acknowledgment that they have received such training and such signed acknowledgment shall be maintained on file by CVS. CVS shall also produce a one-page summary of the Language Assistance Policy to serve as a reference for Pharmacy Staff, and shall post such summary near the point of sale of the Pharmacy of each New York Store.

4.8 **Complaint System**

Within 60 days of the Effective Date, CVS shall develop a system for tracking and responding to complaints from Customers about barriers to effective communication with Pharmacy Staff, which system shall include the capacity to confirm receipt of complaints and provide details of any remedial actions taken in response to the complaints.

4.9 **Advertising**

During the first year following the Effective Date, a majority of all CVS advertisements and promotional materials concerning Pharmacy Services shall state that CVS provides language assistance services to its Customers.

4.10 **Recordkeeping**

CVS shall maintain documents and records sufficient to accurately provide the Monitoring and Reporting information required in paragraphs 5.1 and 5.2, and to permit the analysis of
Customer Primary Languages required in paragraph 4.5.

4.11 Future Research and Advancements

The parties agree that CVS will continue to research and where feasible implement protocols that expand access for Customers who require language assistance services. Moreover, nothing in this Agreement shall prevent CVS from providing services in a Customer’s Primary Language that exceed the requirements of this Agreement.

V. MONITORING AND REPORTING

5.1 Commencing six (6) months following CVS’ full implementation of its new pharmacy system, which shall occur by March 31, 2010, and every six (6) months thereafter during the duration of this Assurance, CVS shall provide the OAG with the following information for each New York Store based on the previous six-month period: the number of prescriptions filled, broken down in percentage terms by the Customer’s Primary Language; the number of Warning Labels printed, broken down in percentage terms by the language in which they were printed; and the number of instructions for use of a prescription drug printed, if provided in some manner other than on the prescription drug label, broken down in percentage terms by the language in which they were printed.

CVS shall retain documents and materials that form the basis of this information for at least six (6) months from the date originally provided to the OAG.

5.2 CVS shall retain an independent examiner at its own cost and acceptable to the OAG to run a monitoring program in which individuals employed by that examiner make unannounced and incognito visits to New York Stores to determine the extent to which CVS is in compliance with the terms of this Agreement. The independent examiner shall have the right to make recommendations for other investigative steps, to ensure compliance with this AOD. CVS and the independent examiner shall submit a monitoring plan for approval by the OAG. Every six (6) months during the life of this Agreement, the independent examiner shall provide the OAG and CVS with a report that describes the visits and its findings.

5.3 Every six (6) months CVS shall provide the OAG with information about any complaints received through the system put in place pursuant to paragraph 4.8, and the steps, if any, that CVS took to address or resolve those complaints.
VI.

JURISDICTION AND OTHER PROVISIONS

6.1 CVS agrees not to take any action or to make or permit to be made any public statement denying, directly or indirectly, any finding in this Assurance or creating the impression that this Assurance is without factual basis. Nothing in this paragraph affects CVS': (a) testimonial obligations; or (b) right to take legal or factual positions in defense of litigation or other legal proceedings to which the OAG is not a party.

6.2 Notwithstanding any provision of this Agreement to the contrary, the OAG may, in its sole discretion, grant written extensions of time for CVS to comply with any provision of this Agreement.

6.3 Where notices of privacy practices required by 45 C.F.R. § 164.520 and/or written offers of counseling required by 8 N.Y.C.R.R. § 63.6(8)(ii)(a) are amended, CVS will be granted a reasonable amount of time to amend its vital documents as described in section 4.6(c) of this Assurance.

6.4 The signatories to this Agreement warrant and represent that they are duly authorized to execute this Agreement and that they have the authority to take all appropriate action required or permitted to be taken pursuant to the Agreement to effectuate its terms.

6.5 All the terms of this Agreement are contractual, and none may be amended or modified except in a writing signed by all parties.

6.6 If CVS desires to modify any of the obligations and requirements set forth in this Agreement, it shall submit in writing its proposed modifications, along with any explanations for the desired changes, for review and approval by the OAG.

6.7 The parties may seek to enforce this Agreement through administrative or judicial enforcement proceedings, including a civil action in federal or state court, as appropriate, seeking specific performance of the provisions of this Agreement. Pursuant to New York Executive Law § 63(15), evidence of a violation of the Assurance will constitute prima facie proof of a violation of the applicable statutes in any civil action or proceeding hereafter commenced by the OAG. In the event of a dispute among the parties regarding any issue arising hereunder, the parties shall attempt in good faith to resolve the dispute before seeking administrative or judicial intervention.

6.8 The failure by the OAG to enforce this entire Agreement or any provision thereof with respect to any deadline or any other provision herein shall not be construed as a waiver of the right of the OAG to enforce other deadlines and provisions of this Agreement.

6.9 This Agreement constitutes the entire agreement among CVS and the OAG on the matters
raised herein, and no other statement, promise or agreement, either written or oral, made by either party or agents of either party that is not contained in this Agreement shall be enforceable.

6.10 Nothing in this Agreement is intended to confer any right, remedy, obligation or liability upon any person or entity other than the parties hereto.

6.11 This Agreement does not apply to any other issues, reviews, or complaints that may be pending before the OAG or any other federal or state agency regarding CVS' compliance with applicable statutes or regulations enforced by the OAG, or any other agency. This Agreement also does not preclude further OAG investigations, inquiries or compliance reviews of CVS. Any matters arising from subsequent reviews or investigations shall be addressed and resolved separately in accordance with the procedures and standards of the statute(s) and implementing regulation(s) applicable to the matter(s) raised.

6.12 CVS shall not retaliate, intimidate, threaten, coerce, or discriminate against any person, including any CVS Customer or Employee, who has filed a complaint, testified, assisted, or participated in any manner in the investigation of the matter addressed in this Agreement.

6.13 This Agreement shall expire three (3) years following the full implementation of the CVS Pharmacy Computer System, which shall occur by March 31, 2010.
IN WITNESS WHEREOF, the parties hereto, intending to be legally bound thereby, have caused this Resolution to be executed, by their duly authorized attorneys or representatives, as of the date and year first written below.

Dated: New York, New York
October 20, 2008

CVS Pharmacy, Inc.
By: Greg Sciarra
   Director, Pharmacy Operations
   One CVS Drive
   Woonsocket, RI 02895

CONSENTED TO:

Dated: New York, New York
October 12, 2008

ANDREW M. CUOMO
Attorney General of the State of New York
By: Alphonso David
   Deputy Bureau Chief

Spencer Freedman
Counsel for Civil Rights

120 Broadway
New York, New York 10271
Tel. (212) 416-8250
Fax. (212) 416-8074
EXHIBIT A
Pharmacy Customer Bill of Rights for Language Services

1. The right to understand all information necessary to ensure the safe and effective use of prescription medications.

2. The right to receive counseling from a pharmacist in the language you speak.

3. The right to interpreter services to ensure that communications with a pharmacist can take place in your language.

4. The right to have vital documents, such as the directions for use of a prescription drug, translated into your language or explained to you by an interpreter.

5. The right to file a complaint with the pharmacy if you do not receive assistance or if any staff member violates these rights.
Testimony Before:

Senate Finance Committee

Assembly Ways & Means Committee

Tuesday, February 8, 2012
10:00 a.m.
Hearing Room B
Legislative Office Building
Albany, NY

Presented By:

Michael Duteau
Chain Pharmacy Association of New York State
Chairman DeFrancisco, Honnon, Farrel, Gottfried and other Members of the panel, my name is Michael Dietsch. I am Vice President of Pharmacy Operations and Government Affairs for Kinney Drugs and Vice Chair of the New York State Board of Pharmacy. I am testifying today on behalf of the Chain Pharmacy Association of New York State. We greatly appreciate the opportunity to testify regarding the Governor’s Proposed FY 2012-13 State Budget as it relates to community pharmacy.

On behalf of our thirteen member companies, we would first like to express our appreciation for the past support and leadership of the Senate and Assembly in restoring a number of proposed cuts to pharmacy reimbursement and other actions in support of community pharmacy. Below we have provided background on the pharmacy industry in New York State including a summary of the history of cuts to community pharmacy enacted over the last decade. Further, we provide our perspective on the 2012-13 Executive Budget followed by our recommendations to expand patient access to necessary health care services while also reducing Medicaid costs. We thank you in advance for your consideration of our comments in this regard.

Introduction/Value of Pharmacy
There are approximately 4,472 community pharmacies, chain and independent, across New York State which collectively employ over 132,280 full and part-time workers including almost 10,719 pharmacists. Chain pharmacies specifically employ 114,927 of the employees in New York and contribute $1.5 billion of the $1.28 billion in total taxes paid by pharmacies to New York State annually. New York’s 2,282 chain pharmacies play a vital role across the state providing high-quality pharmacy care to our residents. The services provided by pharmacies help to keep people healthy and in the community, preventing other escalating healthcare costs such as hospitalizations and emergency room and doctor’s visits.

Medication is particularly important to the management of chronic diseases that require long-term or lifelong therapy. Poor medication adherence costs the nation approximately $290 billion annually — 13% of total healthcare expenditures — and results in avoidable and costly health complications, worsening of disease progression, increased emergency room visits and hospital stays. This inadequate medication adherence rate is associated with about $47 billion annually for drug-related hospitalizations, and estimated 40 percent of nursing home admissions. Community pharmacists are uniquely qualified and positioned to help reduce the problem of poor medication adherence and are skilled to work with patients to manage their medications and chronic conditions. Through well-established relationships with the patient, pharmacists have gained the trust of their patients and have proven to be a reliable source of information to the patient regarding their healthcare needs.

Through services like medication therapy management and administration of immunizations, community pharmacists have the ability to provide quality care that is convenient and easily accessible in virtually every community. Community pharmacists are medication experts with the ability to identify patient-specific medication-related issues and communicate those issues to the patient and their provider. Pharmacists have the ability to educate the patient with the necessary information to improve patient compliance, outcomes, overall quality of care, and reduce overall healthcare costs associated with more costly medical interventions.

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issues to consider with regard to ensuring the accuracy of translated materials. One study published in April 2010 found an error rate of 50% in prescription labels translated into Spanish by pharmacies in the Bronx.

II. **Remove Cause of Action Against Pharmacies:** This proposal permits a cause of action against a pharmacy by aggrieved individuals for failure to receive required services. We believe that this is outrageous. This would create a special right to sue a pharmacy for a particular population (those who are LEP) related to the counseling and other services provided by a pharmacy. Currently, all individuals who feel that they were not counseled or were mistreated may file a complaint with the State Office of Professional Discipline. The Office then investigates the complaint and if found in violation, the pharmacist and/or pharmacy may face fines, revocation of license or a number of other serious actions.

**Recommendation:** The current law is sufficient in this regard, treating all patients who may be aggrieved in the same manner. If the State were to require oral interpretation services in pharmacies, we respectfully request that this right to a cause of action be removed from the language.

III. **Create a Uniform State Standard:** The Executive Budget would allow localities to impose additional or stricter requirements. In addition to the operational concerns that we have with this language, such a provision could result in a patchwork of different language, counseling, labeling and other prescription/pharmacy requirements.

**Recommendation:** If the State were to require oral interpretation services in pharmacies, we believe that it is critical that there be one statewide standard for interpretation services in pharmacy practice to ensure the safety of the public. To that end, the language permitting localities to impose additional requirements should be removed and language should be added to preempt local action, providing one State standard.

IV. **Provide Liability Protection Related to Third Party Contractors:** The Executive Budget permits pharmacies to use pharmacy staff or third party contractors to meet the oral interpretation requirements in the bill. Given the number of languages for which interpretation could be required, pharmacies would likely have no other choice but to use third party contractors. However there are concerns in doing so related to how to ensure the accuracy of interpreted messages and difficulties in terms of the pharmacist trying to answer patient questions. Clearly, critical information could get lost in the translation.

**Recommendation:** If the State were to require oral interpretation services in pharmacies, we strongly urge that the State provide protections to pharmacies by adding language which states that pharmacies are not liable for any issues related to the accuracy of the
APPENDIX C
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<td>26</td>
<td>Portuguese</td>
<td>Assinale este quadrado se você lê ou fala português.</td>
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<td>27</td>
<td>Romanian</td>
<td>Însemnați această căsătă dacă citiți sau vorbiți român este.</td>
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<td>28</td>
<td>Russian</td>
<td>Пометьте этот квадратик, если вы читаете или говорите по-русски.</td>
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<td>29</td>
<td>Serbian</td>
<td>Обележите овaj квадратик уколико читате или говорите српски језик.</td>
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<td>30</td>
<td>Slovak</td>
<td>Označte tento štvorček, ak viete čítať alebo hovoriť po slovensky.</td>
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<td>31</td>
<td>Spanish</td>
<td>Marque esta casilla si lee o habla español.</td>
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<td>32</td>
<td>Tagalog</td>
<td>Markahan itong kwadrado kung kayo ay marunong magbasa o magsalita ng Tagalog.</td>
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<td>33</td>
<td>Thai</td>
<td>ให้เราเครื่องหมายลงในช่องถ้าท่านอ่านหรือพูดภาษาไทย.</td>
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<td>34</td>
<td>Tongan</td>
<td>Maaka 'i he puha ni kapau 'oku ke lau pe lea fakatonga.</td>
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<td>Ukranian</td>
<td>Відмітьте цю клітинку, якщо ви читаєте або говорите українською мовою.</td>
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<td>36</td>
<td>Urdu</td>
<td>آگر آپ اردو پر مبتلا ہوں تو کہو سکتے ہیں مبنی نہیں نہیں؟</td>
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<td>37</td>
<td>Vietnamese</td>
<td>Xin đánh dấu vào ở đây nếu quý vị biết đọc và nói được Việt Ngữ.</td>
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<td>38</td>
<td>Yiddish</td>
<td>באצטננט דעם קעזטל אוניב איב לאיענט אדער רעדט אידיש.</td>
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APPENDIX D
Financial Assistance

If you think you will have trouble paying your hospital bill, you may qualify for a discount. For more information or to apply, see our financial counselor for assistance. Call 000-000-000 or go to room XXXXX. Please advise the financial counselor if you need an interpreter.
Rite Aid News

Rite Aid Now Offers Prescription Bottle Labels In 11 Different Languages

Large 20 - Point Type Labels Also Available

Camp Hill, PA (August 1, 2005) - Prescription bottle labels, which include instructions for taking the medicine, can now be printed in 11 different languages at Rite Aid drugstores nationwide. Non-English speaking Rite Aid patients will no longer have to depend on translation from a friend or relative to make sure they are taking their prescriptions correctly.

Rite Aid pharmacists can now provide labels in English, Spanish, French, Arabic, Korean, Chinese, Japanese, Hindi, Polish, Russian or Portuguese. For patients who prefer larger printed labels to more easily identify their medicines and how to take them, Rite Aid pharmacies are also now equipped to print with a 20- point type versus the typical smaller type.

"Both translation difficulties and not being able to see the type clearly can interfere with patients' ability to take their prescriptions correctly," said Phil Keough, senior vice president of pharmacy operations. "Now our pharmacists can provide all of our patients the tools they need to correctly follow their medication therapy."

In areas with a large non-English speaking population, Rite Aid staffs its pharmacies with bilingual pharmacists or technicians whenever possible.

Rite Aid Corporation (NYSE, PCX: RAD) is one of the nation's leading drugstore chains with annual revenues of $16.8 billion and approximately 3,400 stores in 28 states and the District of Columbia. Information about Rite Aid, including corporate background and press releases, is available through the company's website at www.riteaid.com.

XXX

Contact:

Media:Jody Cook 717-731-6566
May 15, 2009

Michael R. Carter, Regional Manager
Department of Health and Human Services
Office of the Secretary
Office for Civil Rights Region II
Federal Building
26 Federal Plaza
Room 3312
New York, NY 10278

Ref: Transaction Number 06-44385

Dear Mr. Carter:

I am responding to your request for written correspondence confirming recent discussions with OCR in my capacity as Assistant Counsel of Medco Health Solutions, Inc. ("Medco"). To summarize, the U.S. Department of Health and Human Services, Office for Civil Rights ("OCR") received a complaint alleging that Medco has engaged in unlawful discrimination on the basis of national origin. Specifically, it has been alleged that Medco has failed to provide limited English proficient ("LEP") members with meaningful access to mail order pharmacy services and other pharmacy benefit management services provided by Medco.

In connection with the resolution of OCR’s complaint investigation (reference number 06-44385) (the “Complaint”), Medco is willing to implement the following measures to strengthen its provision of language assistance services to LEP members with whom Medco directly communicates:

In late 2008, Medco instituted a project (the “Other Than English Language” project) staffed with a core team of senior level Medco employees (the “Team”). The goal of the Other Than English project is to better capture member language preferences and maintain and utilize those preferences for member communications. In 2009, the project and Team are primarily focused on the Spanish language. However, the Team expects that this will be a multi-year project that will continue to work on languages other than Spanish and will continue to update communication forms and programs to support languages other than English.
The Team’s deliverables for 2009 include the following items:

- Call Center Spanish team expansion was recently accomplished. Currently, Medco has approximately 100 bilingual, Spanish-speaking customer service representatives who are trained to communicate directly in Spanish with Spanish-speaking members. Medco will continue to use the AT&T language line for languages other than Spanish (and for Spanish, during any hours that the Call Center Spanish team is not available).

- Enable the ability for Medco’s customer service representatives to transfer calls to bilingual, Spanish-speaking Regional Consulting Pharmacists who are trained to communicate directly in Spanish with Spanish-speaking members as requested by the patient/member to discuss any pharmacist related information for mail service prescriptions.

- Display language preference indicator in customer service applications that allow representatives to add a language indicator field, making the selected language visible to all users. Ensure the ability to use the member’s language preference is available to drive specific written materials and supports future capability of other documents as translated. Ensure the ability to use the member’s language preference to drive effective outbound calls to members.

- Once a language preference is established by customer service, support the ability to route members with Spanish indicator directly to designated bilingual, Spanish-speaking customer service representatives, bypassing any Voice Response Unit.

- Support the acceptance on the “Medco Standard Eligibility Format” of a member’s language preference. Develop the ability to accept and maintain, at the member level, a language preference indicator and the language requested as passed by the client.

- Create a set of policies and guidelines for both internal and external use, of how and when we will offer communications in other than English. This includes an ongoing assessment/inventory of communication materials that will be offered in languages other than English, and the specific languages that will be supported.

In addition, the Team will be assessing the feasibility of methods to improve the provision of notice to LEP members of the availability of language assistance services from Medco. Some of the initiatives currently being considered include:

- Inclusion of a Spanish footer on all Medco communications (e.g., “Para informarse en espanol llama al 1-800-123-4567”).
- Adding language to the commercial website (similar to the language used on the Medco Medicare Part D website) that notifies members as to the availability of language assistance services. As part of a planned whole web redesign, Medco will also consider whether actual content on the commercial website will be translated and made available in Spanish.

- The printing of certain communications that have English on one side and Spanish on the other.

- The insertion of a Spanish-language buckslip in pharmacy communications.

- Bi-lingual communications targeted based on Medco modeling (Medco uses zip code overlays and other demographic data to identify members who might benefit from a bi-lingual communications).

Finally, Medco is developing a process to ensure that Medco staff at call centers and pharmacies, who are either expected to communicate directly with LEP members in a language other than English, or are expected to function as an interpreter with English-speaking Medco staff, are assessed as to their proficiency in that language and, to the extent that they are expected to function as interpreters, their competency at interpreting. Through the use of the already established Pharmacy Compliance Assessment Team, a risk-based assessment plan will be created. The Pharmacy Compliance Assessment Team will audit against these standards during their on-site visits to the Medco call centers and pharmacies, as appropriate.

As previously discussed with an OCR investigator, Medco will monitor the systems and processes that it implements as a result of the “Other Than English Language” project. This monitoring will include periodic assessments of the effectiveness of such systems and processes. Medco will also train all relevant staff on such systems, processes, policies and procedures.

During the year following the date that OCR issues its closure letter regarding the Complaint, Medco will (through its designated representative) periodically update OCR on significant activities relating to Medco’s implementation of the foregoing measures, including, by way of example, the names and titles of the individuals comprising the Team. Medco understands that OCR has agreed to serve as a technical assistance resource throughout that year, as reasonably necessary and as requested by Medco.

Medco will fully cooperate with your review of this matter. If you have any questions, please do not hesitate to contact me directly at (201) 269-5209.

Very truly yours,

/S/

Paul E. DelloRusso
Assistant Counsel
APPENDIX G
local, tribal, and foreign law enforcement agencies; Federal/State probation and judicial offices; Congress; contract and consulting physicians, including hospitals; and attorneys for claimants.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

The Attorney General has exempted this system from subsections (c)(3) and (4), (d), (e), (f), (g), and (h) of the Privacy Act pursuant to 5 U.S.C. 552a(i). Rules have been promulgated in accordance with the requirements of 5 U.S.C. 553(b), (c), and (e) and have been published in the Federal Register and codified at 28 CFR 16.97(a) and (b).

[FR Doc. 02–15299 Filed 6–17–02; 8:45 am]
BILLING CODE 4410–05–P

DEPARTMENT OF JUSTICE


AGENCY: Department of Justice.

ACTION: Policy guidance document.


DATES: Effective June 12, 2002.


SUPPLEMENTARY INFORMATION: Under DOJ regulations implementing Title VI of the Civil Rights Act of 1964, 42 U.S.C. 2000d, et seq. (Title VI), recipients of Federal financial assistance have a responsibility to ensure meaningful access to their programs and activities by persons with limited English proficiency (LEP). See 28 CFR 42.104(b)(2). Executive Order 13166, reprinted at 65 FR 50121 (August 16, 2000), directs each Federal agency that extends assistance subject to the requirements of Title VI to publish guidance for its respective recipients clarifying that obligation. Executive Order 13166 further directs that all such guidance documents be consistent with the compliance standards and framework detailed in DOJ Policy Guidance entitled “Enforcement of Title VI of the Civil Rights Act of 1964—National Origin Discrimination Against Persons with Limited English Proficiency.” See 65 FR 50123 (August 16, 2000).

Initial guidance on DOJ recipients' obligations to take reasonable steps to ensure access by LEP persons was published on January 16, 2001. See 66 FR 3834. That guidance document was republished for additional public comment on January 18, 2002. See 67 FR 2671. Based on public comments filed in response to the January 18, 2002 republication, DOJ published revised draft guidance for public comment on April 18, 2002. See 67 FR 19237.

DOJ received 24 comments in response to its April 18, 2002 publication of revised draft guidance on DOJ recipients' obligations to take reasonable steps to ensure access to programs and activities by LEP persons. The comments reflected the views of individuals, organizations serving LEP populations, organizations favoring the use of the English language, language assistance service providers, and state agencies. While many comments identified areas for improvement and/or revision, the overall response to the draft DOJ Recipient LEP Guidance was favorable. Taken together, a majority of the comments described the draft guidance as incorporating “reasonable standards” or “helpful provisions” providing “useful suggestions instead of mandatory requirements” reflecting “common sense” and a “more measured tone” over prior LEP guidance documents.

Two of the comments urged withdrawal of the draft guidance as unsupported by law. In response, the Department notes here as it did in the draft Recipient LEP Guidance published on April 18, 2002 that the Department's commitment to implement Title VI through regulations reaching language barriers is long-standing and is unaffected by recent judicial action precluding individuals from bringing judicial actions seeking to enforce those agency regulations. See 67 FR at 19238–19239. This particular policy guidance clarifies existing statutory and regulatory requirements for LEP persons by providing a description of the factors recipients should consider in fulfilling their responsibilities to LEP persons.

Of the remaining 22 comments, three supported adoption of the draft guidance as published, and 19, while supportive of the guidance and the Department's leadership in this area, suggested modifications which would, in their view, either (1) clarify the application of the flexible compliance standard incorporated by the draft guidance to particular areas or situations, or (2) provide a more definitive statement of the minimal compliance standards in this area. Several areas were raised in more than one comment. In the order most often raised, those common areas of comment were (1) recipient language assistance plans, (2) use of informal interpreters, (3) written translation safe harbors, and (4) cost considerations. The comments in each of these areas are summarized and discussed below.

Recipient Language Assistance Plans.

A large number of comments recommended that written language assistance plans (LEP Plans) be required of all recipients. The Department is cognizant of the value of written LEP plans in documenting a recipient's compliance with its obligation to ensure meaningful access by LEP persons, and in providing a framework for the provision of reasonable and necessary language assistance to LEP persons. The Department is also aware of the related training, operational, and planning benefits most recipients would derive from the generation and maintenance of an updated written language assistance plan for use by its employees. In the large majority of cases, the benefits flowing from a written language assistance plan has caused or will likely cause recipients to develop such plans, with varying degrees of detail, such written plans. Even small recipients with limited contact with LEP persons would likely benefit from having a plan in place to assure that, when the need arises, staff have a written plan to turn to—even if it is only how to access a telephonic or community-based interpretation service—when determining what language services to provide and how to provide them.

However, the fact that the vast majority of the Department's recipients already have or will likely develop a written LEP plan to reap its many benefits does not necessarily mean that every recipient, however small its staff, limited its resources, or focused its services, will realize the same benefits and thus must follow an identical path. Without clear evidence suggesting that the absence of written plans for every single recipient is impeding accomplishment of the goal of meaningful access, the Department elects at this juncture to strongly recommend but not require written language assistance plans. The
Department stresses in this regard that neither the absence of a requirement of written LEP plans in all cases nor the election by an individual recipient against drafting a plan obviates the underlying obligation on the part of each recipient to provide, consistent with Title VI, the Title VI regulations, and the DOJ Recipient LEP Guidance, reasonable, timely, and appropriate language assistance to the LEP populations each serves.

While the Department continues to believe that the Recipient LEP Guidance strikes the correct balance between recommendations and requirements in this area, the Department has revised the introductory paragraph of Section VII of the Recipient LEP Guidance to acknowledge a recipient’s discretion in drafting a written LEP plan yet to emphasize the many benefits that weigh in favor of such a written plan in the vast majority of cases.

Informal Interpreters. As in the case of written LEP plans, a large number of the comments called for the incorporation of more definitive language strongly discouraging or severely limiting the use of informal interpreters such as family members, guardians, caretakers, friends, or fellow inmates or detainees. Some recommended that the draft guidance be revised to prohibit the use of informal interpreters except in limited or emergency situations. A common subtheme running through many of these comments was a concern regarding the technical and ethical competency of such interpreters to ensure meaningful and appropriate access at the level and of the type contemplated under the DOJ Recipient LEP Guidance.

As in the case of written LEP plans, the Department believes that the DOJ Recipient LEP Guidance provides sufficient guidance to allow recipients to strike the proper balance between the many situations where the use of informal interpreters is inappropriate, and the few situations where the transitory and/or limited use of informal interpreters is necessary and appropriate in light of the nature of a service or benefit being provided and the factual context in which that service or benefit is being provided. Nonetheless, the Department concludes that the potential for the inappropriate use of informal interpreters or, conversely, its unnecessary avoidance, can be minimized through additional clarifications in the DOJ Recipient LEP Guidance. Towards that end, the subsection titled “Use of Family Members, Friends, Other Inmates, or Other Detainees as Interpreters,” of Section VII.A. of the DOJ Recipient LEP Guidance has been revised to include guardians and caretakers among the potential class of informal interpreters, to note that beneficiaries who elect to provide their own informal interpreter do so at their own expense, to clarify that reliance on informal interpreters should not be part of any recipient LEP plan, and to expand the discussion of the special considerations that should guide a recipient’s limited reliance on informal interpreters.

Safe Harbors. Several comments focused on safe harbor and vital documents provisions of the written translations section of the DOJ Recipient LEP Guidance. A few comments observed that the safe harbor standard set out in the Recipient LEP Guidance was too high, potentially permitting recipients to avoid translating several critical types of vital documents (e.g., notices of denials of benefits or rights, leases, rules of conduct, etc.). In contrast, another comment pointed to this same standard as support for the position that the safe harbor provision was too low, potentially requiring a large recipient to incur extraordinary fiscal burdens to translate all documents associated with the program or activity.

The decision as to what program-related documents should be translated into languages other than English is a difficult one. While documents generated by a recipient may be helpful in understanding a program or activity, not all are critical or vital to ensuring meaningful access by beneficiaries generally and LEP persons specifically. Some documents may create or define legally enforceable rights or responsibilities on the part of individual beneficiaries (e.g., leases, rules of conduct, notices of benefit denials, etc.). Others, such as application or certification forms, solicit important information required to establish or maintain eligibility to participate in a Federally-assisted program or activity. And for some programs or activities, written documents may be the core benefit or service provided by the program or activity. Moreover, some programs or activities may be specifically focused on providing benefits or services to significant LEP populations. Finally, a recipient may elect to solicit vital information orally as a substitute for written documents. For example, many state unemployment insurance programs are transitioning away from paper-based application and certification forms in favor of telephone-based systems. Also, certain languages (e.g., Hmong) are oral rather than written, and thus a high percentage of such LEP speakers will likely be unable to read translated documents or written instructions since it is only recently that such languages have been converted to a written form. Each of these factors should play a role in deciding what documents should be translated, what target languages other than English are appropriate, or even whether more effective alternatives to a continued reliance on written documents to obtain or process vital information exist.

As has been emphasized elsewhere, the Recipient LEP Guidance is not intended to provide a definitive answer governing the translation of written documents for all recipients applicable in all cases. Rather, it is intended to provide one, but not necessarily the only, point of reference for when a recipient should consider translations of documents (or the implementation of alternatives to such documents) in light of its particular program or activity, the document or information in question, and the potential LEP populations served. In furtherance of this purpose, the safe harbor and vital documents provisions of the Recipient LEP Guidance, the Department sought to provide one, but not necessarily the only, point of reference for when a recipient should consider translations of documents (or the implementation of alternatives to such documents) in light of its particular program or activity, the document or information in question, and the potential LEP populations served. In furtherance of this purpose, the safe harbor and vital documents provisions of the Recipient LEP Guidance have been revised to clarify the elements of the flexible translation standard, and to acknowledge that distinctions can and should be made between frequently-encountered and less commonly-encountered languages when identifying languages for translation.

Costs Considerations. A number of comments focused on cost considerations as an element of the Department’s flexible four-factor analysis for identifying and addressing the language assistance needs of LEP
persons. While none urged that costs be excluded, some comments expressed concern that a recipient could use cost as a basis for avoiding otherwise reasonable and necessary language assistance to LEP persons. In contrast, a few comments suggested that the flexible fact-dependent compliance standard incorporated by the DOJ Recipient LEP Guidance, when combined with the desire of most recipients to avoid the risk of noncompliance, could lead some large, state-wide recipients to incur unnecessary or inappropriate fiscal burdens in the face of already strained program budgets. The Department is mindful that cost considerations could be inappropriately used to avoid providing otherwise reasonable and necessary language assistance. Similarly, cost considerations could be inappropriately ignored or minimized to justify the provision of a particular level or type of language service where less costly equally effective alternatives exist. The Department also does not dismiss the possibility that the identified need for language services might be quite costly for certain types of recipients in certain communities, particularly if they have not been keeping up with the changing needs of the populations they serve over time.

The potential for possible abuse of cost considerations by some does not, in the Department’s view, justify its elimination as a factor in all cases when determining the appropriate “mix” of reasonable language assistance services determined to be necessary under the DOJ Recipient LEP Guidance to ensure meaningful access by LEP persons to Federally assisted programs and activities. The Department continues to believe that costs are a legitimate consideration in identifying the reasonableness of particular language assistance measures, and that the DOJ Recipient LEP Guidance identifies the appropriate framework through which costs are to be considered.

In addition to the four larger concerns noted above, the Department has substituted, where appropriate, technical or stylistic changes that more clearly articulate, in the Department’s view, the underlying principle, guideline, or recommendation detailed in the Guidance. In addition, the Guidance has been modified to expand the definition of “courts” to include administrative adjudications conducted by a recipient; to acknowledge that English language instruction is an important adjunct to (but not substitute for) the obligation to ensure access to Federally assisted programs and activities by all eligible persons; and to clarify the Guidance’s application to activities undertaken by a recipient either voluntarily or under contract in support of a Federal agency’s functions.

After appropriate revision based on a careful consideration of the comments, with particular focus on the common concerns summarized above, the Department adopts final “Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons.” The text of this final guidance document appears below.

It has been determined that this Guidance, which supplants existing Guidance on the same subject previously published at 66 FR 3834 (January 16, 2001), does not constitute a regulation subject to the rulemaking requirements of the Administrative Procedure Act, 5 U.S.C. 553.

Dated: June 12, 2002.

R. Alexander Acosta,
Principal Deputy Assistant Attorney General,
Civil Rights Division.

I. Introduction

Most individuals living in the United States read, write, speak and understand English. There are many individuals, however, for whom English is not their primary language. For instance, based on the 2000 census, over 26 million individuals speak Spanish and almost 7 million individuals speak an Asian or Pacific Island language at home. If these individuals have a limited ability to read, write, speak, or understand English, they are limited English proficient, or “LEP.” While detailed data from the 2000 census has not yet been released, 26% of all Spanish-speakers, 29.9% of all Chinese-speakers, and 28.2% of all Vietnamese-speakers reported that they spoke English “not well” or “not at all” in response to the 1990 census.

Language for LEP individuals can be a barrier to accessing important benefits or services, understanding and exercising important rights, complying with applicable responsibilities, or understanding other information provided by Federally funded programs and activities. The Federal Government funds an array of services that can be made accessible to otherwise eligible LEP persons. The Federal Government is committed to improving the accessibility of these programs and activities to eligible LEP persons, a goal that reinforces its equally important commitment to promoting programs and activities designed to help individuals learn English. Recipients should not overlook the long-term positive impacts of incorporating or offering English as a Second Language (ESL) programs in parallel with language assistance services. ESL courses can serve as an important adjunct to a proper LEP plan. However, the fact that ESL classes are made available does not obviate the statutory and regulatory requirement to provide meaningful access for those who are not yet English proficient. Recipients of Federal financial assistance have an obligation to reduce language barriers that can preclude meaningful access by LEP persons to important government services.

In certain circumstances, failure to ensure that LEP persons can effectively participate in or benefit from Federally assisted programs and activities may violate the prohibition under Title VI of the Civil Rights Act of 1964, 42 U.S.C. 2000d and Title VI regulations against national origin discrimination. The purpose of this policy guidance is to assist recipients in fulfilling their responsibilities to provide meaningful access to LEP persons under existing law. This policy guidance clarifies existing legal requirements for LEP persons by providing a description of the factors recipients should consider in fulfilling their responsibilities to LEP persons. These are the same criteria DOJ will use in evaluating whether recipients are in compliance with Title VI and Title VI regulations.

The Department of Justice’s role under Executive Order 13166 is unique. The Order charges DOJ with responsibility for providing LEP Guidance to other Federal agencies and for ensuring consistency among each agency-specific guidance. Consistency among Departments of the Federal government is particularly important. Inconsistency or contradictory guidance could confuse recipients of Federal funds and needlessly increase costs without rendering the meaningful access for LEP persons that this

1 DOJ recognizes that many recipients had language assistance programs in place prior to the issuance of Executive Order 13166. This policy guidance provides a uniform framework for a recipient to integrate, formalize, and assess the continued vitality of these existing and possibly additional reasonable efforts based on the nature of its program or activity, the current needs of the LEP populations it encounters, and its prior experience in providing language services in the community it serves.

2 The policy guidance is not a regulation but rather a guide. Title VI and its implementing regulations require that recipients take responsible steps to ensure meaningful access by LEP persons. This guidance provides an analytical framework that recipients may use to determine how best to comply with statutory and regulatory obligations to provide meaningful access to the benefits, services, information, and other important portions of their programs and activities for individuals who are limited English proficient.
Guidance is designed to address. As with most government initiatives, this requires balancing several principles. While this Guidance discusses that balance in some detail, it is important to note the basic principles behind that balance. First, we must ensure that Federally-assisted programs aimed at the American public do not leave some behind simply because they face challenges communicating in English. This is of particular importance because, in many cases, LEP individuals form a substantial portion of those encountered in Federally-assisted programs. Without these steps, certain smaller grantees may well choose not to participate in Federally assisted programs, threatening the critical functions that the programs strive to provide. To that end, the Department plans to continue to provide assistance and guidance in this important area. In addition, DOJ plans to work with representatives of language assistance measures, resources and cost-saving approaches developed with respect to its own Federally conducted programs and activities can be effectively shared or otherwise made available to recipients, particularly small businesses, small local governments, and small non-profits. An interagency working group on LEP has developed a Web site, www.lep.gov, to assist in disseminating this information to recipients, Federal agencies, and the communities being served. Many commentators have noted that some have interpreted the case of Alexander v. Sandoval, 532 U.S. 275 (2001), as impliedly striking down the regulations promulgated under Title VI that form the basis for the part of Executive Order 13166 that applies to Federally assisted programs and activities. We have taken the position that this is not the case, and will continue to do so. Accordingly, we will strive to ensure that Federally assisted programs and activities work in a way that is effective for all eligible beneficiaries, including those with limited English proficiency.

II. Legal Authority

Section 601 of Title VI of the Civil Rights Act of 1964, 42 U.S.C. 2000d, provides that no person shall “on the ground of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance.” Section 601 authorizes and directs Federal agencies that are empowered to extend Federal financial assistance to any program or activity “to effectuate the provisions of [section 601] by issuing rules, regulations, or orders of general applicability.” 42 U.S.C. 2000d-1. Department of Justice regulations promulgated pursuant to section 602 forbid recipients from “utilizing criteria or methods of administration which have the effect of subjecting individuals to discrimination because of their race, color, or national origin, or have the effect of defeating or substantially impairing accomplishment of the objectives of the program as respects individuals of a particular race, color, or national origin.” 28 CFR 42.104(b)(2).

The Supreme Court, in Lau v. Nichols, 414 U.S. 563 (1974), interpreted regulations promulgated by the former Department of Health, Education, and Welfare, including a regulation similar to that of DOJ, 45 CFR 80.3(b)(2), to hold that Title VI prohibits conduct that has a disproportionate effect on LEP persons because such conduct constitutes national-origin discrimination. In Lau, a San Francisco school district that had a significant number of non-English speaking students of Chinese origin was required to take reasonable steps to provide them with a meaningful opportunity to participate in Federally funded educational programs.

On August 11, 2000, Executive Order 13166 was issued. “Improving Access to Services for Persons with Limited English Proficiency.” 65 FR 50121 (August 16, 2000). Under that order, every Federal agency that provides financial assistance to non-Federal entities must publish guidance on how their recipients can provide meaningful access to LEP persons and thus comply with Title VI regulations forbidding funding recipients from “restrict[ing] an individual in any way in the enjoyment of any advantage or privilege enjoyed by others receiving any service, financial aid, or other benefit under the program,” or from “utiliz[ing] criteria or methods of administration which have the effect of subjecting individuals to discrimination because of their race, color, or national origin, or have the effect of defeating or substantially impairing accomplishment of the objectives of the program as respects individuals of a particular race, color, or national origin.”

On that same day, DOJ issued a general guidance document addressed to “Executive Agency Civil Rights Officers” setting forth general principles for agencies to apply in developing guidance documents for recipients pursuant to the Executive Order.


Subsequently, Federal agencies raised questions regarding the requirements of the Executive Order, especially in light of the Supreme Court’s decision in Alexander v. Sandoval, 532 U.S. 275 (2001). On October 26, 2001, Ralph F. Boyd, Jr., Assistant Attorney General for the Civil Rights Division, issued a memorandum for “Heads of Departments and Agencies, General Counsels and Civil Rights Directors.” This memorandum clarified and reaffirmed the DOJ LEP Guidance in light of Sandoval. The Assistant Attorney General stated that because Sandoval did not invalidate any Title VI regulations that proscribe conduct that has a disparate impact on covered groups—the types of regulations that form the legal basis for the part of Executive Order 13166 that applies to Federally assisted programs and activities—the Executive Order remains in force.

Pursuant to Executive Order 13166, DOJ developed its own guidance document for recipients and initially

3 The memorandum noted that some commentators have interpreted Sandoval as impliedly striking down the disparate-impact regulations promulgated under Title VI that form the basis for the part of Executive Order 13166 that applies to Federally assisted programs and activities. See, e.g., Sandoval, 532 U.S. at 286, 286 n.6 ("[W]e assume for purposes of this decision that section 602 confers the authority to promulgate disparate-impact regulations; * * * We cannot help observing, however, how strange it is to say that disparate-impact regulations are 'inspired by, at the service of, and inseparably intertwined with' Sec. 601 * * * when Sec. 601 permits the very behavior that the regulations forbid."). The memorandum, however, made clear that DOJ disagreed with the commentators’ interpretation. Sandoval holds principally that there is no private right of action to enforce Title VI disparate-impact regulations. It did not address the validity of Executive or Executive Order 13166 or otherwise limit the authority and responsibility of Federal grant agencies to enforce their own implementing regulations.

This guidance document is thus published pursuant to Executive Order 13166 and supplants the January 16, 2001 publication in light of the public comment received and Assistant Attorney General Boyd’s October 26, 2001 clarifying memorandum.

III. Who Is Covered?

Department of Justice regulations, 28 CFR 42.104(b)(2), require all recipients of Federal financial assistance from DOJ to provide meaningful access to LEP persons. Federal financial assistance includes grants, training, use of equipment, donations of surplus property, and other assistance. Recipients of DOJ assistance include, for example:

- Police and sheriffs’ departments
- Departments of corrections, jails, and detention facilities, including those recipients that house detainees of the Immigration and Naturalization Service
- Courts
- Certain non profit agencies with law enforcement, public safety, and victim assistance missions;
- Other entities with public safety and emergency service missions.

Subrecipients likewise are covered when Federal funds are passed through from one recipient to a subrecipient.

Coverage extends to a recipient’s entire program or activity, i.e., to all parts of a recipient’s operations. This is true even if only one part of the recipient receives the Federal assistance. Example: DOJ provides assistance to a state department of corrections to improve a particular prison facility. All of the operations of the entire state department of corrections—not just the particular prison—are covered.

Finally, some recipients operate in jurisdictions in which English has been declared the official language. Nonetheless, these recipients continue to be subject to Federal nondiscrimination requirements, including those applicable to the provision of Federally assisted services to persons with limited English proficiency.

IV. Who Is a Limited English Proficient Individual?

Individuals who do not speak English as their primary language and who have a limited ability to read, write, speak, or understand English can be limited English proficient, or “LEP,” entitled to language assistance with respect to a particular type of service, benefit, or program.

Examples of populations likely to include LEP persons who are encountered and/or served by DOJ recipients and should be considered when planning language services include, but are not limited to:

- Persons who are in the custody of the recipient, including juveniles, detainees, wards, and inmates.
- Persons subject to or serviced by law enforcement activities, including, for example, suspects, violated, witnesses, victims, those subject to immigration-related investigations by recipient law enforcement agencies, and community members seeking to participate in crime prevention or awareness activities.
- Persons who encounter the court system.
- Parents and family members of the above.

V. How Does a Recipient Determine the Extent of Its Obligation To Provide LEP Services?

Recipients are required to take reasonable steps to ensure meaningful access to their programs and activities by LEP persons. While designed to be a flexible and fact-dependent standard, the starting point is an individualized assessment that balances the following four factors: (1) The number or proportion of LEP persons eligible to be served or likely to be encountered by the program or grantee; (2) the frequency with which LEP individuals come in contact with the program; (3) the nature and importance of the program, activity, or service provided by the program to people’s lives; and (4) the resources available to the grantee/recipient and costs. As indicated above, the intent of this guidance is to suggest a balance that ensures meaningful access by LEP persons to critical services while not imposing undue burdens on small business, small local governments, or small nonprofits.

After applying the above four-factor analysis, a recipient may conclude that different language assistance measures are sufficient for the different types of programs or activities in which it engages. For instance, some of a recipient’s activities will be more important than others and/or have greater impact on or contact with LEP persons, and thus may require more in the way of language assistance. The flexibility that recipients have in addressing the needs of the LEP populations they serve does not diminish, and should not be used to minimize, the obligation that those needs be addressed. DOJ recipients should apply the following four factors to the various kinds of contacts that they have with the public to assess language needs and decide what reasonable steps they should take to ensure meaningful access for LEP persons.

(1) The Number or Proportion of LEP Persons Served or Encountered in the Eligible Service Population

One factor in determining what language services recipients should provide is the number or proportion of LEP persons from a particular language group served or encountered in the eligible service population. The greater the number or proportion of these LEP persons, the more likely language services are needed. Ordinarily, persons “eligible to be served, or likely to be directly affected,” by a recipient’s program or activity are those who are served or encountered in the eligible service population. This population will be program-specific, and includes persons who are in the geographic area that has been approved by a Federal grant agency as the recipient’s service area. However, where, for instance, a precinct serves a large LEP population, the appropriate service area is most likely the precinct, and not the entire population served by the department. Where no service area has previously been approved, the relevant service area may be that which is approved by state or local authorities or designated by the

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[4] Pursuant to Executive Order 13166, the meaningful access requirement of the Title VI regulations and the four-factor analysis set forth in the DOJ LEP Guidance are to additionally apply to the programs and activities of Federal agencies, including the Department of Justice.

[5] As used in this guidance, the word “court” or “courts” includes administrative adjudicatory systems or administrative hearings administered or conducted by a recipient.

[6] However, if a Federal agency were to decide to terminate Federal funds based on noncompliance with Title VI or its regulations, only funds directed to the particular program or activity that is out of compliance would be terminated. 42 U.S.C. 2000d–1.
It is advisable to consider the recipient that serves LEP persons daily. Different types of language services in that language are different than those expected from a recipient that serves an LEP person on a one-time basis will be very predictable. It may be as simple as being prepared to use one of the commercially-available telephonic interpretation services to obtain immediate interpreter services. In applying this standard, recipients should take care to consider whether appropriate outreach to LEP persons could increase the frequency of contact with LEP language groups.

(3) The Nature and Importance of the Program, Activity, or Service Provided by the Program

The more important the activity, information, service, or program, or the greater the possible consequences of the contact to the LEP individuals, the more likely language services are needed. The obligations to communicate rights to a person who is arrested or to provide medical services to an ill or injured inmate differ, for example, from those to provide bicycle safety courses or recreational programming. A recipient needs to determine whether denial or delay of access to services or information could have serious or even life-threatening implications for the LEP individual. Decisions by a Federal, State, or local entity to make an activity compulsory, such as particular educational programs in a correctional facility or the communication of Miranda rights, can serve as strong evidence of the program’s importance.

(4) The Resources Available to the Recipient and Costs

A recipient’s level of resources and the costs that would be imposed on it may have an impact on the nature of the steps it should take. Smaller recipients with more limited budgets are not expected to provide the same level of language services as larger recipients with larger budgets. In addition, “reasonable steps” may cease to be reasonable where the costs imposed substantially exceed the benefits.

Resource availability, however, can often be reduced by technological advances; the sharing of language assistance materials and services among and between recipients, advocacy groups, and Federal grant agencies; and reasonable business practices. Where appropriate, training bilingual staff to act as interpreters and translators, information sharing through industry groups, telephonic and video conferencing interpretation services, pooling resources and standardizing documents to reduce translation needs, using qualified translators and interpreters to ensure that documents need not be “fixed” later and that inaccurate interpretations do not cause delay or other costs, centralizing interpreter and translator services to achieve economies of scale, or the formalized use of qualified community volunteers, for example, may help reduce costs.8

Recipients should carefully explore the most cost-effective means of delivering competent and accurate language services before limiting services due to resource concerns. Large entities and those entities serving a significant number or proportion of LEP persons should ensure that their resource limitations are well-substantiated before using this factor as a reason to limit language assistance. Such recipients may find it useful to be able to articulate, through documentation or in some other reasonable manner, their process for determining that language services would be limited based on resources or costs.

This four-factor analysis necessarily implicates the “mix” of LEP services required. Recipients have two main ways to provide language services: Oral interpretation either in person or via telephone interpretation service (hereinafter “interpretation”) and written translation (hereinafter “translation”). Oral interpretation can range from on-site interpreters for critical services provided to a high volume of LEP persons to access through commercially-available telephonic interpretation services. Written translation, likewise, can range from translation of an entire document to translation of a short description of the document. In some cases, language services should be made available on an expedited basis while in others the LEP individual may be referred to another office of the recipient for language assistance.

The correct mix should be based on what is both necessary and reasonable in light of the four-factor analysis. For
Demonstrate proficiency in and ability to communicate information accurately in both English and in the other language and identify and employ the appropriate mode of interpreting (e.g., consecutive, simultaneous, summarization, or sight translation); have knowledge in both languages of any specialized terms or concepts peculiar to the entity’s program or activity and of any particularized vocabulary and phraseology used by the LEP person; and understand and follow confidentiality and impartiality rules to the same extent the recipient employee for whom they are interpreting and/or to the extent their position requires.

Understand and adhere to their role as interpreters without deviating into a role as counselor, legal advisor, or other roles (particularly in court, administrative hearings, or law enforcement contexts).

Some recipients, such as courts, may have additional self-imposed requirements for interpreters. Where individual rights depend on precise, complete, and accurate interpretation or translations, particularly in the contexts of courtrooms and custodial or other police interrogations, the use of certified interpreters is strongly encouraged. Where such proceedings are lengthy, the interpreter will likely need breaks and team interpreting may be appropriate to ensure accuracy and to prevent errors caused by mental fatigue of interpreters.

While quality and accuracy of language services is critical, the quality and accuracy of language services is nonetheless part of the appropriate mix of LEP services required. The quality and accuracy of language services in a prison hospital emergency room, for example, must be extraordinarily high, while the quality and accuracy of language services in a bicycle safety class need not meet the same exacting standards.

Finally, when interpretation is needed and is reasonable, it should be provided in a timely manner. To be meaningfully effective, language assistance should be timely. While there is no single definition for “timely” applicable to all types of interactions at all times by all types of recipients, one clear guide is that the language assistance should be provided at a time and place that avoids the effective denial of the service, benefit, or right at issue or the imposition of an undue burden on or delay in important rights, benefits, or services to the LEP person. For example, when the timeliness of services is important, such as with certain activities of DOJ recipients providing law enforcement, health, and safety services, and when important legal rights are at issue, a recipient would likely not be providing meaningful access if it had one bilingual staffer available one day a week to provide the service. Such conduct would likely result in delays for LEP persons that would be significantly greater than those for English proficient persons. Conversely, where access to or exercise of a service, benefit, or right is not effectively precluded by a reasonable delay, language assistance can likely be delayed for a reasonable period.

**Hiring Bilingual Staff.** When particular languages are encountered often, hiring bilingual staff offers one of the best, and often most economical, options. Recipients can, for example, fill public contact positions, such as 911 operators, police officers, guards, or program directors, with staff who are bilingual and competent to communicate directly with LEP persons in their language. If bilingual staff are also used to interpret between English speakers and LEP persons, or to orally interpret written documents from English into another language, they should be competent in the skill of interpreting. Being bilingual does not necessarily mean that a person has the ability to interpret. In addition, there may be times when the role of the bilingual employee may conflict with the role of an interpreter (for instance, a bilingual law clerk would probably not be able to perform effectively the role of a courtroom or administrative hearing interpreter and law clerk at the same time, even if the law clerk were a qualified interpreter). Effective management strategies, including any appropriate adjustments in assignments and protocols for using bilingual staff, can ensure that bilingual staff are fully and appropriately utilized. When bilingual staff cannot meet all of the language service obligations of the recipient, the recipient should turn to other options.
Hiring Staff Interpreters. Hiring interpreters may be most helpful when there is a frequent need for interpreting services in one or more languages. Depending on the facts, sometimes it may be necessary and reasonable to provide on-site interpreters to provide accurate and meaningful communication with an LEP person.

Contracting for Interpreters. Contract interpreters may be a cost-effective option when there is no regular need for a particular language skill. In addition to commercial and other private providers, many community-based organizations and mutual assistance associations provide interpretation services for particular languages. Contracting with and providing training regarding the recipient’s programs and processes to these organizations can be a cost-effective option for providing language services to LEP persons from those language groups.

Using Telephone Interpreter Lines. Telephone interpreter service lines often offer accurate and meaningful assistance in many different languages. They may be particularly appropriate where the mode of communicating with an English proficient person would also be over the phone. Although telephonic interpretation services are useful in many situations, it is important to ensure that, when using such services, the interpreters used are competent to interpret any technical or legal terms specific to a particular program that may be important parts of the conversation. Nuances in language and non-verbal communication can often assist an interpreter and cannot be recognized over the phone. Video teleconferencing may sometimes help to resolve this issue where necessary. In addition, where documents are being discussed, it is important to give telephonic interpreters adequate opportunity to review the document prior to the discussion and any logistical problems should be addressed.

Using Community Volunteers. In addition to consideration of bilingual staff, staff interpreters, or contract interpreters (either in-person or by telephone) as options to ensure meaningful access by LEP persons, use of recipient-coordinated community volunteers, working with, for instance, community-based organizations may provide a cost-effective supplemental language assistance strategy under appropriate circumstances. They may be particularly useful in providing language access for a recipient’s less critical programs and activities. To the extent the recipient relies on community volunteers, it is often best to use volunteers who are trained in the information or services of the program and can communicate directly with LEP persons in their language. Just as with all interpreters, community volunteers used to interpret between English speakers and LEP persons, or to orally translate documents, should be competent in the skill of interpreting and knowledgeable about applicable confidentiality and impartiality rules. Recipients should consider formal arrangements with community-based organizations that provide volunteers to address these concerns and to help ensure that services are available more regularly.

Use of Family Members, Friends, Other Inmates, or Other Detainees as Interpreters. Although recipients should not plan to rely on an LEP person’s family members, friends, or other informal interpreters to provide meaningful access to important programs and activities, where LEP persons so desire, they should be permitted to use, at their own expense, an interpreter of their own choosing (whether a professional interpreter, family member, friend, other inmate, other detainee) in place of or as a supplement to the free language services expressly offered by the recipient. LEP persons may feel more comfortable when a trusted family member, friend, or other inmate acts as an interpreter. In addition, in exigent circumstances that are not reasonably foreseeable, temporary use of interpreters not provided by the recipient may be necessary. However, with proper planning and implementation, recipients should be able to avoid most such situations.

Recipients, however, should take special care to ensure that family, legal guardians, caretakers, and other informal interpreters are appropriate in light of the circumstances and subject matter of the program, service or activity, including protection of the recipient’s own administrative or enforcement interest in accurate interpretation. In many circumstances, family members (especially children), friends, other inmates or other detainees are not competent to provide quality and accurate interpretations. Issues of confidentiality, privacy, or conflict of interest may also arise. LEP individuals may feel uncomfortable revealing or describing sensitive, confidential, or potentially embarrassing medical, law enforcement (e.g., sexual or violent assaults), family, or financial information to a family member, friend, or member of the local community. In such a setting, an LEP person’s use of family, friends, or others may be appropriate.

If the LEP person voluntarily chooses to provide his or her own interpreter, a recipient should consider whether a record of that choice and of the recipient’s offer of assistance is appropriate. Where precise, complete, regarding the voluntary nature, conflicts of interest, and privacy issues surrounding the use of inmates and detainees as interpreters, particularly where an important right, benefit, service, disciplinary concern, or access to personal or law enforcement information is at stake. In some situations, inmates could potentially misuse information they obtained in interpreting for other inmates. In addition to ensuring competency and accuracy of the interpretation, recipients should take these special circumstances into account when determining whether an inmate or detainee makes a knowing and voluntary choice to use another inmate or detainee as an interpreter.
and accurate interpretations or translations of information and/or testimony are critical for law enforcement, adjudicatory, or legal reasons, or where the competency of the LEP person’s interpreter is not established, a recipient might decide to provide its own, independent interpreter, even if an LEP person wants to use his or her own interpreter as well. Extra caution should be exercised when the LEP person chooses to use a minor as the interpreter. While the LEP person’s decision should be respected, there may be additional issues of competency, confidentiality, or conflict of interest when the choice involves using children as interpreters. The recipient should take care to ensure that the LEP person’s choice is voluntary, that the LEP person is aware of the possible problems if the preferred interpreter is a minor child, and that the LEP person knows that a competent interpreter could be provided by the recipient at no cost.

B. Written Language Services (Translation)

Translation is the replacement of a written text from one language (source language) into an equivalent written text in another language (target language).

What Documents Should be Translated? After applying the four-factor analysis, a recipient may determine that an effective LEP plan for its particular program or activity includes the translation of vital written materials into the language of each frequently-encountered LEP group eligible to be served and/or likely to be affected by the recipient’s program.

Such written materials could include, for example:

- Consent and complaint forms
- Intake forms with the potential for important consequences
- Written notices of rights, denial, loss, or decreases in benefits or services, parole, and other hearings
- Notices of disciplinary action
- Notices advising LEP persons of free language assistance
- Prison rule books
- Written tests that do not assess English language competency, but test competency for a particular license, job, or skill for which knowing English is not required
- Applications to participate in a recipient’s program or activity or to receive recipient benefits or services.

Whether or not a document (or the information it solicits) is “vital” may depend upon the importance of the program, information, encounter, or service involved, and the consequence to the LEP person if the information in question is not provided accurately or in a timely manner. For instance, applications for bicycle safety courses should not generally be considered vital, whereas applications for drug and alcohol counseling in prison could be considered vital. Where appropriate, recipients are encouraged to create a plan for consistently determining, over time and across its various activities, what documents are “vital” to the meaningful access of the LEP populations they serve.

Classifying a document as vital or non-vital is sometimes difficult, especially in the case of outreach materials like brochures or other information on rights and services. Awareness of rights or services is an important part of “meaningful access.” Lack of awareness that a particular program, right, or service exists may effectively deny LEP individuals meaningful access. Thus, where a recipient is engaged in community outreach activities in furtherance of its activities, it should regularly assess the needs of the populations frequently encountered or affected by the program or activity to determine whether certain critical outreach materials should be translated. Community organizations may be helpful in determining what outreach materials may be most helpful to translate. In addition, the recipient should consider whether translations of outreach material may be made more effective when done in tandem with other outreach methods, including utilizing ethnic media, schools, religious, and community organizations to spread a message.

Sometimes a document includes both vital and non-vital information. This may be the case when the document is very large. It may also be the case when the title and a phone number for obtaining more information on the contents of the document in frequently-encountered languages other than English is critical, but the document is sent out to the general public and cannot reasonably be translated into many languages. Thus, vital information may include, for instance, the provision of information in appropriate languages other than English regarding where a LEP person might obtain an interpretation or translation of the document.

Into What Languages Should Documents be Translated? The languages spoken by the LEP individuals with whom the recipient has contact determine the languages into which vital documents should be translated. A distinction should be made, however, between languages that are frequently encountered by a recipient and less commonly-encountered languages. Many recipients serve communities in large cities or across the country. They regularly serve LEP persons who speak dozens and sometimes over 100 different languages. To translate all written materials into all of those languages is unrealistic. Although recent technological advances have made it easier for recipients to store and share translated documents, such an undertaking would incur substantial costs and require substantial resources. Nevertheless, well-substantiated claims of lack of resources to translate all vital documents into dozens of languages do not necessarily relieve the recipient of the obligation to translate those documents into at least several of the more frequently-encountered languages and to set benchmarks for continued translations into the remaining languages over time.

As a result, the extent of the recipient’s obligation to provide written translations of documents should be determined by the recipient on a case-by-case basis, looking at the totality of the circumstances in light of the four-factor analysis. Because translation is a one-time expense, consideration should be given to whether the upfront cost of translating a document (as opposed to oral interpretation) should be amortized over the likely lifespan of the document when applying this four-factor analysis.

Safe Harbor: Many recipients would like to ensure with greater certainty that they comply with their obligations to provide written translations in languages other than English.

Paragraphs (a) and (b) outline the circumstances that can provide a “safe harbor” for recipients regarding the requirements for translation of written materials. A “safe harbor” means that if a recipient provides written translations under these circumstances, such action will be considered strong evidence of compliance with the recipient’s written-translations obligations.

The failure to provide written translations under the circumstances outlined in paragraphs (a) and (b) does not mean there is non-compliance. Rather, they provide a common starting point for recipients to consider whether and at what point the importance of the service, benefit, or activity involved; the nature of the information sought; and the number or proportion of LEP persons served call for written translations of commonly-used forms into frequently-encountered languages other than English. Thus, these paragraphs merely provide a guide for recipients that would like greater certainty of compliance than can be
provided by a fact-intensive, four-factor analysis.

Example: Even if the safe harbors are not used, if written translation of a certain document(s) would be so burdensome as to defeat the legitimate objectives of its program, the translation of the written materials is not necessary. Other ways of providing meaningful access, such as effective oral interpretation of certain vital documents, might be acceptable under such circumstances.

Safe Harbor. The following actions will be considered strong evidence of compliance with the recipient’s written-translation obligations:

(a) The DOJ recipient provides written translations of vital documents for each eligible LEP language group that constitutes five percent or 1,000, whichever is less, of the population of persons eligible to be served or likely to be affected or encountered. Translation of other documents, if needed, can be provided orally; or

(b) If there are fewer than 50 persons in a language group that reaches the five percent trigger in (a), the recipient does not translate vital written materials but provides written notice in the primary language of the LEP language group of the right to receive competent oral interpretation of those written materials, free of cost.

These safe harbor provisions apply to the translation of written documents only. They do not affect the requirement to provide meaningful access to LEP individuals through competent oral interpreters where oral language services are needed and are reasonable. For example, correctional facilities should, where appropriate, ensure that prison rules have been explained to LEP inmates, at orientation, for instance, prior to taking disciplinary action against them.

Competence of Translators. As with oral interpreters, translators of written documents should be competent. Many of the same considerations apply. However, the skill of translating is very different from the skill of interpreting, and a person who is a competent interpreter may or may not be competent to translate.

Particularly where legal or other vital documents are being translated, competence can often be achieved by use of certified translators. Certification or accreditation may not always be possible or necessary. Competence can often be ensured by having a second, independent translator “check” the work of the primary translator. Alternatively, one translator can translate the document, and a second, independent translator could translate it back into English to check that the appropriate meaning has been conveyed. This is called “back translation.”

Translators should understand the expected reading level of the audience and, where appropriate, have fundamental knowledge about the target language group’s vocabulary and phraseology. Sometimes direct translation of materials results in a translation that is written at a much more difficult level than the English language version or has no relevant equivalent meaning. Community organizations may be able to help consider whether a document is written at a good level for the audience. Likewise, consistency in the words and phrases used to translate terms of art, legal, or other technical concepts helps avoid confusion by LEP individuals and may reduce costs. Creating or using already-created glossaries of commonly-used terms may be useful for LEP persons and translators and cost effective for the recipient. Providing translators with examples of previous accurate translations of similar material by the recipient, other recipients, or Federal agencies may be helpful.

While quality and accuracy of translation services is critical, the quality and accuracy of translation services is nonetheless part of the appropriate mix of LEP services required. For instance, documents that are simple and have no legal or other consequence for LEP persons who rely on them may use translators that are less skilled than documents with legal or other information upon which reliance has important consequences (including, e.g., information or documents of DOJ recipients regarding certain law enforcement, health, and safety services and certain legal rights).

The permanent nature of written translations, however, imposes additional responsibility on the recipient to ensure that the quality and accuracy permit meaningful access by LEP persons.

VII. Elements of Effective Plan on Language Assistance for LEP Persons

After completing the four-factor analysis and deciding what language assistance services are appropriate, a recipient should develop an implementation plan to address the identified needs of the LEP populations they serve. Recipients have considerable flexibility in developing this plan. The development and maintenance of a periodically-updated written plan on language assistance for LEP persons (“LEP plan”) for use by recipient employees serving the public will likely be the most appropriate and cost-effective means of documenting compliance and providing a framework for the provision of timely and reasonable language assistance.

Moreover, such written plans would likely provide additional benefits to a recipient’s managers in the areas of training, administration, planning, and budgeting. These benefits should lead most recipients to document in a written LEP plan their language assistance services, and how staff and LEP persons can access those services. Despite these benefits, certain DOJ recipients, such as recipients serving very few LEP persons and recipients with very limited resources, may choose not to develop a written LEP plan. However, the absence of a written LEP plan does not obviate the underlying obligation to ensure meaningful access by LEP persons to a recipient’s program or activities. Accordingly, in the event that a recipient elects not to develop a written plan, it should consider alternative ways to articulate in some other reasonable manner a plan for providing meaningful access. Entities having significant contact with LEP persons, such as schools, religious organizations, community groups, and groups working with immigrants can be very helpful in providing important input into this planning process from the beginning.

The following five steps may be helpful in designing an LEP plan and are typically part of effective implementation plans:

(1) Identifying LEP Individuals Who Need Language Assistance

The first two factors in the four-factor analysis require an assessment of the number or proportion of LEP individuals eligible to be served or
encountered and the frequency of encounters. This requires recipients to identify LEP persons with whom it has contact.

One way to determine the language of communication is to use language identification cards (or “I speak cards”), which invite LEP persons to identify their language needs to staff. Such cards, for instance, might say “I speak Spanish” in both Spanish and English, “I speak Vietnamese” in both English and Vietnamese, etc. To reduce costs of compliance, the Federal government has made a set of these cards available on the Internet. The Census Bureau “I speak card” can be found and downloaded at http://www.usdoj.gov/crt/cor/13166.htm. When records are normally kept of past interactions with members of the public, the language of the LEP person can be included as part of the record. In addition to helping employees identify the language of LEP persons they encounter, this process will help in future applications of the first two factors of the four-factor analysis. In addition, posting notices in commonly encountered languages notifying LEP persons of language assistance will encourage them to self-identify.

(2) Language Assistance Measures

An effective LEP plan would likely include information about the ways in which language assistance will be provided. For instance, recipients may want to include information on at least the following:

- Types of language services available.
- How staff can obtain those services.
- How to respond to LEP callers.
- How to respond to written communications from LEP persons.
- How to respond to LEP individuals who have in-person contact with recipient staff.
- How to ensure competency of interpreters and translation services.

(3) Training Staff

Staff should know their obligations to provide meaningful access to information and services for LEP persons. An effective LEP plan would likely include training to ensure that:

- Staff know about LEP policies and procedures.
- Staff having contact with the public (or those in a recipient’s custody) are trained to work effectively with in-person and telephone interpreters.

Recipients may want to include this training as part of the orientation for new employees. It is important to ensure that all employees in public contact positions (or having contact with those in a recipient’s custody) are properly trained. Recipients have flexibility in deciding the manner in which the training is provided. The more frequent the contact with LEP persons, the greater the need will be for in-depth training. Staff with little or no contact with LEP persons may only have to be aware of an LEP plan. However, management staff, even if they do not interact regularly with LEP persons, should be fully aware of and understand the plan so they can reinforce its importance and ensure its implementation by staff.

(4) Providing Notice to LEP Persons

Once an agency has decided, based on the four factors, that it will provide language services, it is important for the recipient to let LEP persons know that those services are available and that they are free of charge. Recipients should provide this notice in a language LEP persons will understand. Examples of notification that recipients should consider include:

- Posting signs in intake areas and other entry points. When language assistance is needed to ensure meaningful access to information and services, it is important to provide notice in appropriate languages in intake areas or initial points of contact so that LEP persons can learn how to access those language services. This is particularly true in areas with high volumes of LEP persons seeking access to certain health, safety, or law enforcement services or activities run by DOJ recipients. For instance, signs in intake offices could state that free language assistance is available. The signs should be translated into the most common languages encountered. They should explain how to get the language help.14
  - Stating in outreach documents that language services are available from the agency. Announcements could be in, for instance, brochures, booklets, and in outreach and recruitment information. These statements should be translated into the most common languages and could be “tagged” onto the front of common documents.
  - Working with community-based organizations and other stakeholders to inform LEP individuals of the recipients’ services, including the availability of language assistance services.
  - Using a telephone voice mail menu. The menu could be in the most common

14The Social Security Administration has made such signs available at http://www.ssa.gov/multilanguage/langlist1.htm. These signs could, for example, be modified for recipient use.
Appendix A—Application of LEP Guidance for DOJ Recipients to Specific Types of Recipients

While a wide range of entities receive Federal financial assistance through DOJ, most of DOJ’s assistance goes to law enforcement agencies, including state and local police and sheriffs’ departments, and to state departments of corrections. Sections A and B below provide examples of how these two major types of DOJ recipients might apply the four-factor analysis. Section C provides examples for other types of recipients. The examples in this Appendix are not meant to be exhaustive and may not apply in many situations.

The requirements of the Title VI regulations, as clarified by this Guidance, supplement, but do not supplant, constitutional and other statutory or regulatory provisions that may require LEP services. Thus, a proper application of the four-factor analysis and compliance with the Title VI regulations does not replace constitutional or other statutory protections mandating warnings and notices in languages other than English in the criminal justice context. Rather, this Guidance clarifies the Title VI regulatory obligation to address, in appropriate circumstances and in a reasonable manner, the language assistance needs of LEP individuals beyond those required by the Constitution or statutes and regulations other than the Title VI regulations.

A. State and Local Law Enforcement

Appendix A further explains how law enforcement recipients can apply the four factors to a range of encounters with the public. The responsibility for providing language services differs with different types of encounters.

Appendix A helps recipients identify the population they should consider when considering the types of services to provide. It then provides guidance and examples of applying the four factors. For instance, it gives examples on how to apply this guidance to:

- Receiving and responding to requests for help
- Enforcement stops short of arrest and field investigations
- Custodial interrogations
- Intake/detention Community outreach

B. Departments of Corrections

Appendix A also helps departments of corrections understand how to apply the four factors. For instance, it gives examples of LEP access in:

- Intake
- Disciplinary action
- Health and safety
- Participation in classes or other programs affecting length of sentence
- English as a Second Language (ESL) Classes
- Community corrections programs

C. Other Types of Recipients

Appendix A also applies the four factors and gives examples for other types of recipients. Those include, for example:

- Courts
- Juvenile Justice Programs

- Domestic Violence Prevention/Treatment Programs

The common thread running through these and other interactions between the public and law enforcement is the exchange of information. Where police and sheriffs’ departments receive Federal financial assistance, these departments have an obligation to provide LEP services to LEP individuals to ensure that they have meaningful access to the system, including, for example, understanding rights and accessing police assistance. Language barriers can, for instance, prevent victims from effectively reporting crimes to the police and hinder police investigations of reported crimes. For example, failure to communicate effectively with a victim of domestic violence can result in reliance on the batterer or a minor child and failure to identify and protect against harm.

Many police and sheriffs’ departments already provide language services in a wide variety of circumstances to obtain information effectively, to build trust and
relationships with the community, and to contribute to the safety of law enforcement personnel. For example, many police departments already have available printed Miranda rights in languages other than English as well as interpreters available to inform LEP persons of their rights and to interpret police interviews. In areas where significant LEP populations reside, law enforcement officials already may have forms and notices in languages other than English or they may employ bilingual law enforcement officers, intake personnel, counselors, and support staff. These experiences can form a strong basis for applying the four-factor analysis and complying with the Title VI regulations.

1. General Principles

The touchstone of the four-factor analysis is reasonableness based upon the specific purposes, needs, and capabilities of the law enforcement service under review and an appreciation of the nature and particularized needs of the LEP population served. Accordingly, the analysis cannot provide a single uniform answer on how service to LEP persons must be provided in all programs or activities in all situations or whether such services need be provided at all. Knowledge of local conditions and community needs becomes critical in determining the type and level of language services needed.

Before giving specific examples, several general points should assist law enforcement in correctly applying the analysis to the wide range of services employed in their particular jurisdictions.

a. Permanent Versus Seasonal Populations

In many communities, resident populations change over time or season. For example, in some resort communities, populations swell during peak vacation periods, many times exceeding the number of permanent residents of the jurisdiction. In other communities, primarily agricultural, seasonal and temporary populations of workers will require increased law enforcement services during the relevant harvest season. This dynamic demographic ebb and flow can also dramatically change the size and nature of the LEP community likely to come into contact with law enforcement personnel. Thus, law enforcement officials may not want to limit their analysis to numbers and percentages of permanent residents. In assessing factor one—the number or proportion of LEP individuals—police departments should consider any significant but temporary changes in a jurisdiction’s demographics.

Example: A rural jurisdiction has a permanent population of 30,000, 7% of which is Hispanic. Based on demographic data and on information from the contiguous school district, of that number, only 15% are estimated to be LEP individuals. Thus, the total estimated permanent LEP population is 315 or approximately 1% of the total permanent population. Under the four-factor analysis, a sheriffs’ department could reasonably conclude that the small number of LEP persons makes the affirmative translation of documents and/or employment of bilingual staff unnecessary. However, during the spring and summer harvest seasons, the local population swells to 40,000 due to the influx of seasonal agricultural workers. Of this transitional number, about 75% are Hispanic and about 50% of that number are LEP individuals. This information comes from the schools and a local migrant worker community group. Thus, during the harvest season, the jurisdiction’s LEP population increases to over 10% of all residents. In this case, the department may want to consider whether it is required to translate vital written documents into Spanish. In addition, this increase in LEP population during those seasons makes it important for the jurisdiction to review its interpretation services to ensure meaningful access for LEP individuals.

b. Target Audiences

For most law enforcement services, the target audience is non-LEP rather than programmatic terms. However, some services may be targeted to reach a particular audience (e.g., elementary school children, elderly, residents of high crime areas, minority communities, small business owners/operators, ivory tusk thieves, those who are HIV positive). In the larger geographic area covered by a police department, certain precincts or portions of precincts may have concentrations of LEP persons. In these cases, even if the overall number or proportion of LEP individuals in the district is low, the frequency of contact may be foreseeably higher for certain areas or programs. Thus, the second factor—frequency of contact—should be considered in light of the specific program or the geographic area being served.

Example: A police department that receives funding from the DOJ Office of Justice Programs initiates a program to increase awareness and understanding of police services among elementary school age children in high crime areas of the jurisdiction. This program involves “Officer in the Classroom” presentations at elementary schools located in areas of high poverty. The program is estimated to include only 3% LEP individuals; however, the LEP population at the target schools is 35%, the vast majority of whom are Vietnamese speakers. In applying the four-factor analysis, the higher LEP language group populations of the target schools and the frequency of contact within the program with LEP students in those schools, not the LEP population generally, should be used in determining the nature of the LEP needs of that particular program.

Further, because the Vietnamese LEP population is concentrated in one or two main areas of town, the police department should consider whether to apply the four-factor analysis to the services provided by the police department.

c. Importance of Service/Information

Given the critical role law enforcement plays in maintaining quality of life and property, traditional law enforcement and protective services rank high on the critical/non-critical continuum. However, this does not mean that information about, or provided by, each of the myriad services and activities performed by law enforcement officials must be available in languages other than English. While clearly important to the ultimate success of law enforcement, certain community outreach activities do not have the same direct impact on the provision of core law enforcement services as the activities of 911 lines or law enforcement officials’ ability to respond to requests for assistance while on patrol, to communicate basic information to suspects, etc. Nevertheless, with the rising importance of community partnerships and community-based programming as a law enforcement technique, the need for language services with respect to these programs should be considered in applying the four-factor analysis.

d. Interpreters

Just as with other recipients, law enforcement recipients have a variety of options for providing language services. Under certain circumstances, interpreters are required and recipients should provide competent interpreter services free of cost to the LEP person, LEP persons should be advised that they may choose either to secure the assistance of an interpreter of their own choosing, at their own expense, or a competent interpreter provided by the recipient. If the LEP person decides to provide his or her own interpreter, the provision of this choice to the LEP person and the LEP person’s election should be documented in any written record generated with respect to the LEP person. While an LEP person may sometimes look to bilingual family members or friends or other persons with whom they are comfortable for language assistance, there are many situations where an LEP person might want to rely upon recipient-supplied interpretative services. For example, such individuals may not be available when and where they are needed, or may not have the ability to interpret program-specific technical information. Alternatively, an individual may feel uncomfortable revealing or describing sensitive, confidential, or potentially embarrassing medical, law enforcement (e.g., sexual or violent assaults), family, or financial information to a family member, friend, or member of the local community. Similarly, there may be situations where a recipient’s own interests justify the provision of an interpreter regardless of whether the LEP individual also provides his or her own interpreter. For example, where precise and complete and accurate translations of information and/or testimony are critical for law enforcement, adjudicatory or legal reasons, a recipient might decide to provide its own, independent interpreter, even if an LEP person wants to use their own interpreter as well.

In emergency situations that are not reasonably foreseeable, the recipient may have to temporarily rely on non-recipient-provided language services. Reliance on children is especially discouraged unless...
there is an extreme emergency and no preferable interpreters are available. While all language services need to be competent, the greater the potential consequences, the greater the need to monitor interpretation services for quality. For instance, it is increasingly clear that interpreters in custodial interrogations be highly competent to translate legal and other law enforcement concepts, as well as be extremely accurate in their interpretation. It may be sufficient, however, for a desk clerk who is not skilled at interpreting to help an LEP person figure out to whom he or she needs to talk about setting up a neighborhood watch.

2. Applying the Four-Factor Analysis Along the Law Enforcement Continuum

While all police activities are important, the four-factor analysis requires some prioritizing so that language services are targeted where most needed because of the nature and importance of the particular law enforcement activity involved. In addition, because of the “reasonableness” standard, and frequency of contact and resources/costs factors, the obligation to provide language services increases where the importance of the activity is greater. Under this framework, then, critical areas for language assistance could include 911 calls, custodial interrogation, and health and safety issues for persons within the control of the police. These activities should be considered the most important under the four-factor analysis. Systems for receiving and investigating complaints from the public are important. Often very important are routine patrol activities, receiving non-emergency information regarding potential crimes, and ticketing. Community outreach activities are hard to categorize, but generally they do not rise to the same level of importance as the other activities listed. However, with the importance of community partnerships and community-based programming and law enforcement techniques in mind, the need for language services with respect to these programs should be considered in applying the four-factor analysis.

Police departments have a great deal of flexibility in determining how to best address their outreach to LEP populations. a. Receiving and Responding to Requests for Assistance

LEP persons must have meaningful access to police services when they are victims of or witnesses to alleged criminal activity. Effective reporting systems transform victims, witnesses, or bystanders into assistants in law enforcement and investigation processes. Given the critical role the public plays in reporting crimes or directing limited law enforcement resources to time-sensitive emergency or public safety situations, efforts to address the language assistance needs of LEP individuals could have a significant impact on improving responsiveness, effectiveness, and safety.

Emergency service lines for the public, or 911 lines, operated by agencies that receive Federal financial assistance must be accessible to persons who are LEP. This will mean different things to different jurisdictions. For instance, in large cities with significant LEP communities, the 911 line may have operators who are bilingual and capable of accurately interpreting in high stress situations. Smaller cities or areas with small LEP populations should still have a plan for serving callers who are LEP, but the LEP plan and training orders may involve a telephonic interpretation service that is fast enough and reliable enough to attend to the emergency situation, or include some other accommodation short of hiring bilingual operators.

Example: A large city provides bilingual operators for the emergency lines for the public, or 911 service, and uses a commercial telephone interpretation service when it receives calls from LEP persons who speak other languages. Ten percent of the city’s population is LEP, and sixty percent of the LEP population is within the city’s borders. Because of the diffuse nature of these communities, the city has a 311 Center that has Spanish speaking operators available, and uses a commercial telephone interpretation service when to use 311 instead of 911. These actions constitute strong evidence of compliance.

b. Enforcement Stops Short of Arrest and Field Investigations

Field enforcement includes, for example, traffic stops, pedestrian stops, serving warrants and restraining orders, Terry stops, field investigations, and safety and availability of phone access where other options are not successful. Nevertheless, the ability of law enforcement agencies to discharge fully and effectively their enforcement and crime interdiction mission requires the ability to communicate instructions, commands, and notices. For example, a routine traffic stop can become a difficult situation if an officer is unable to communicate effectively the reason for the stop, the need for identification or other information, and the meaning of any written citation. Requests for consent to search are meaningless if the request is not understood. Similarly, crowd control commands will be wholly ineffective where significant numbers of people in a crowd cannot understand the meaning of law enforcement commands.

Given the wide range of possible situations in which law enforcement in the field can take place, it is impossible to equip every officer with the tools necessary to respond to every possible LEP scenario. Rather, in applying the four factors to field enforcement, the goal should be to implement measures that address the language needs of significant LEP populations in the most likely, common, and important situations, as consistent with the recipients’ resources and costs.

Example: A police department serves a jurisdiction with a significant number of LEP individuals residing in one or more precincts, and it is routinely asked to provide...
c. Custodial Interrogations

Custodial interrogations of unrepresented LEP individuals trigger constitutional rights that this Guidance is not designed to address. Given the importance of being able to communicate effectively under such circumstances, law enforcement recipients should ensure competent and free language services for all individuals in such situations. Law enforcement agencies are strongly encouraged to create a written plan on language assistance for LEP persons in this area. In addition, in formulating a plan for effectively communicating with LEP individuals, jurisdictions should strongly consider whether qualified independent interpreters would be more appropriate during custodial interrogations than law enforcement personnel themselves.2

Example: A large city police department institutes an LEP plan that requires arresting officers to procure a qualified interpreter for any custodial interrogation, notification of rights, or taking of a formal statement where the suspect’s legal rights could be adversely impacted. When considering whether an interpreter is qualified, the LE plan discourages use of police officers as interpreters in interrogations except under circumstances in which the LEP individual is informed of the officer’s dual role and the reliability of the interpretation is verified, such as, for example, where the officer has been trained and tested in interpreting and tape recordings are made of the entire interview. In determining whether an interpreter is qualified, the jurisdiction uses the analysis noted above. These actions would constitute strong evidence of compliance.

d. Intake/Detention

State or local law enforcement agencies that arrest LEP persons should consider the inherent communication impediments to gathering information from the LEP arrestee through an intake or booking process. Aside from the basic information, such as the LEP arrestee’s name and address, law enforcement agencies should evaluate their ability to communicate with the LEP arrestee about his or her medical condition. Because medical screening questions are commonly used to elicit information on the arrestee’s medical needs, suicidal inclinations, presence of contagious diseases, potential illness, resulting symptoms upon withdrawal from certain medications, or the need to segregate the arrestee from other prisoners, it is important for law enforcement agencies to consider how to communicate effectively with an LEP arrestee at this stage. In jurisdictions with few bilingual officers or in situations where the LEP person speaks a language not encountered very frequently, telephonic interpretation services may provide the most cost-effective and efficient method of communication.

e. Community Outreach

Community outreach activities increasingly are recognized as important to the ultimate success of more traditional

1. General Principles

Departments of corrections also have a wide variety of options in providing translation services appropriate to the particular situation. Bilingual staff competent in interpreting, in person or by phone, pose one option. Additionally, particular prisons may have agreements with local colleges and universities, interpreter services, and for community organizations to provide paid or volunteer competent translators under agreements of confidentiality and impartiality. Telephonic interpretation services may offer a prudent oral interpreting option for prisons with very few and/or infrequent prisons in a particular language group. Reliance on fellow prisoners is generally not appropriate. Reliance on fellow prisoners should only be an option in unforeseeable emergency circumstances; whether the LEP inmate has meaningful access within a prison run by a private or other entity with which the department has entered into a contract. The department may provide the staff and materials necessary to provide required language services, or it may choose to require the entity with which it contracted to provide the services itself.

2. Applying the Four Factors Along the Corrections Continuum

As with law enforcement activities, critical and predictable contact with LEP individuals poses the greatest obligation for language services. Correctional facilities have somewhat greater abilities to assess the language needs of those they encounter, although inmate populations may change rapidly in some areas. Contact affecting health and safety, length of stay, and discipline likely present the most critical situations under the four-factor analysis.

a. Assessment

Each department of corrections that receives Federal financial assistance must assess the number of LEP prisoners who are in the system, in which prisons they are located, and the languages he or she speaks. Each prisoner’s LEP status, and the language he or she speaks, should be placed in his or her file. Although this Guidance and Title VI are not meant to address literacy levels, agencies should be aware of literacy problems so that LEP services are provided in a way that is meaningful and useful (e.g., translated written materials are of little use to a nonliterate inmate). After the initial assessment, new LEP prisoners should be identified at intake or orientation, and the data should be updated accordingly.

b. Intake/Orientation

Intake/Orientation plays a critical role not merely in the system’s identification of LEP prisoners, but in providing those prisoners with fundamental information about their
circumstances. As noted previously, fellow prisoners under those circumstances. As noted previously, fellow prisoners under those circumstances. As noted previously, fellow prisoners under those circumstances. As noted previously, fellow prisoners under those circumstances. As noted previously, fellow prisoners under those circumstances. As noted previously, fellow prisoners under those circumstances. As noted previously, fellow

Prisons providing health services should refer to the Department of Health and Human Services’ guidance regarding health care providers’ Title VI and Title VI regulatory obligations, as well as with this Guidance. Health care services are obviously extremely important and access to those services is complicated by the four-factor analysis. If, for instance, a prison serves a high proportion of LEP individuals who speak Spanish, then the prison health care provider should likely have available qualified bilingual medical staff or interpreters versed in medical terms. If the population of LEP individuals is low, then the prison may choose instead, for example, to rely on a local community volunteer program that provides qualified interpreters through a university. Due to the different nature of medical situations, only in unpredictable emergency situations or in non-emergency cases where the inmate has waived rights to a non-inmate interpreter would the use of other bilingual inmates be appropriate.

Example: The department of corrections in a state with a 5% Haitian Creole-speaking LEP population receives Federal financial assistance to expand one of its prisons. The department of corrections has developed an intake video in Haitian Creole and another in Spanish for all of the prisons within the department to use when orienting new prisoners who are LEP and speak one of those languages. In addition, the department provides inmates with an opportunity to ask questions and discuss intake information through either bilingual staff who are competent in interpreting and who are present at the orientation or who are patched in by phone to act as interpreters. The department also has an agreement whereby some of its prisons house a small number of INS detainees. For those detainees or other inmates who are LEP and do not speak English or Spanish, the department has created a list of sources for interpreting, including department staff, contract interpreters, university resources, and a telephonic interpretation service. Each person receives at least an oral explanation of their rights, opportunities, and responsibilities. These actions constitute strong evidence of compliance. Example: A department of corrections that receives Federal financial assistance determines that, even though the state in which it resides has a law declaring English the official language, it should still ensure that LEP prisoners understand the rules, rights, and opportunities and have meaningful access to important information and services at the state prisons. Despite the state’s official English law, the Title VI regulations apply to the department’s prisons.

c. Disciplinary Action

When a prisoner who is LEP is the subject of disciplinary action, the prison, where appropriate, should provide language assistance. That assistance should ensure that the LEP prisoner had adequate notice of the rule in question and is meaningfully able to understand and participate in the process afforded prisoners under those circumstances. As noted previously, follow


But recipients should not overlook the long-term positive impacts of incorporating or offering ESL programs in parallel with language assistance services as one possible strategy for ensuring meaningful access. ESL courses can serve as an important adjunct to a proper LEP plan in prisons because, as prisoners gain proficiency in English, fewer language services are needed. However, the fact that ESL classes are made available does not obviate the need to provide meaningful access for prisoners who are not yet English proficient.

g. Community Corrections

This guidance also applies to community corrections programs that receive Federal financial assistance. For them, the most frequent contact with LEP individuals will be with an offender, a victim, or the family members of either, but may also include witnesses and community members in the area in which a crime was committed.

As with other recipient activities, community corrections programs should apply the four factors and determine areas where language services are most needed and reasonable. Important recipient activities include, for example: interviews; explaining conditions of probation/release; developing case plans; setting up referrals for services; regular supervision contacts; outlining violations of probation/parole and recommendations; and making adjustments to the case plan. Competent oral language services for LEP persons are important for each of these types of communication. Recipients have great flexibility in determining how to provide those services. Just as with all language services, it is important that language services be competent. Some knowledge of the legal system may be necessary in certain circumstances. For example, special attention should be given to the technical interpretation skills of the interpreter used when obtaining information from an offender during pre-sentence and violation of probation/parole investigations or in other circumstances in which legal terms and the results of inaccuracies could impose an enormous burden on the LEP person.

In addition, just as with other recipients, corrections programs should identify vital written materials for probation and parole that should be translated when a significant number or proportion of LEP individuals that speak a particular language is encountered. Vital documents in this context could include, for instance: probation/parole department descriptions and grievance procedures, offender rights information, the pre-sentence/release investigation report, notices of alleged violations, sentencing/release orders, including conditions of parole, and victim impact statement questionnaires.

C. Other Types of Recipients

DOJ provides Federal financial assistance to many other types of entities and programs, including, for example, courts, juvenile justice programs, shelters for victims of domestic violence, and domestic violence prevention programs. The Title VI regulations and this Guidance apply to those
entities. Examples involving some of those recipients follow:  

1. Courts

Application of the four-factor analysis requires recipient courts to ensure that LEP parties and witnesses receive competent language services, consistent with the four-factor analysis. At a minimum, every effort should be taken to ensure competent interpretation for LEP individuals during all hearings, trials, and motions during which the LEP individual must and/or may be present. When a recipient court appoints an attorney to represent an LEP defendant, the court should ensure that either the attorney is proficient in the LEP person’s language or that a competent interpreter is provided during consultations between the attorney and the LEP person.

Many states have created or adopted certification procedures for court interpreters. This is one way for recipients to ensure competency of interpreters. Where certification is available, courts should consider carefully the qualifications of interpreters who are not certified. Courts will not, however, always be able to find a certified interpreter, particularly for less frequently encountered languages. In a courtroom or administrative hearing setting, the use of informal interpreters, such as family members, friends, and caretakers, would not be appropriate.

Example: A state court receiving DOJ Federal financial assistance has frequent contact with LEP individuals as parties and witnesses, but has experienced a shortage in certified interpreters. To broaden the range of languages encountered, State court officials work with training and testing consultants to develop the number of certified interpreters available in the top several languages spoken by LEP individuals in the state. Because resources are sparse and the development of tests expensive, state court officials decide to partner with other states that have already established agreements to share proficiency testing and to develop new ones together. The state court officials also look to other existing resources and plans for bilingual or codes of professional conduct for interpreters; mandatory orientation and basic training for interpreters; interpreter proficiency tests in Spanish and Vietnamese language interpretation; a written test in English for interpreters in all languages covering professional responsibility, basic legal term definitions, court procedures, etc. They are considering working with other states to expand testing certification programs in coming years to include several other less frequently encountered languages. These actions constitute strong evidence of compliance.

Many individuals, while able to communicate in English to some extent, are still LEP insofar as ability to understand the terms and precise language of the courtroom. Courts should consider carefully whether a person will be able to understand and communicate effectively in the stressful role of a witness or party and in situations where knowledge of language subtleties and/or technical terms and concepts are involved or where key determinations are made based on credibility.

Example: Judges in a county court receiving Federal financial assistance have adopted a voir dire for determining a witness’ need for an interpreter. The voir dire avoids questions that could be answered with “yes” or “no.” It includes questions about comfort level in English, and questions that require active response, such as: “How did you come to court today?” etc. The judges also ask the witness more complicated conceptual questions to determine the extent of the person’s proficiency in English. These actions constitute strong evidence of compliance.

Example: A court encounters a domestic violence victim who is LEP. Even though the court is located in a state where English has been declared the official language, it employs a competent interpreter to ensure meaningful access to the state’s official English law, the Title VI regulations apply to the court.

When courts experience low numbers or proportions of LEP individuals from a particular language group and infrequent contact with that language group, creation of a new certification test for interpreters may be overly burdensome. In such cases, other methods should be used to determine the competency of interpreters for the court’s purposes.

Example: A witness in a county court in a large city speaks Urdu and not English. The jurisdiction has no court interpreter certification testing for Urdu language interpreters because very few LEP individuals encountered speak Urdu and there is no such test available through other states or organizations. However, a non-certified interpreter is available and has been given the standard English-language test on court processes and interpreter ethics. The judge brings in a second, independent, bilingual Urdu-speaking person from a local university, and asks the prospective interpreter to interpret the judge’s conversation with the second individual. The judge then asks the second Urdu speaker a series of questions designed to determine whether the interpreter accurately interpreted their conversation. Given the infrequent contact, the low number and proportion of Urdu LEP individuals in the area, and the high cost of providing certification tests for Urdu interpreters, this “second check” solution may be one appropriate way of ensuring meaningful access to the LEP individual.

Example: In order to minimize the necessity of the type of intense judicial intervention on the issue of quality noted in the previous example, the court administrators have worked closely with interpreter and translator associations, the bar, judges, and community groups, have developed and disseminated a stringent set of qualifications for court interpreters. The state has adopted a certification test in several languages. A questionnaire and qualifications process helps identify qualified interpreters even when certified interpreters are not available to meet a particular language need. Thus, the court administrators create a pool from which judges and attorneys can choose. A team of court personnel, judges, interpreters, and others have developed a recommended interpreter oath and a set of frequently asked questions and answers regarding court interpreting that have been provided to judges and clerks. The frequently asked questions include information regarding the types of interpreting (consecutive, simultaneous, summary, and sight translations) and the professional standards for use of each one, and suggested questions for determining whether an LEP witness is effectively able to communicate through the interpreter.

Another key to successful use of interpreters in the courtroom is to ensure that everyone in the process understands the role of the interpreter.

Example: Judges in a recipient court administer a standard oath to each interpreter and make a statement to the jury that the role of the interpreter is to interpret, verbatim, the questions posed to the witness and the witness’ response. The jury should focus on the words, not the non-verbal, of the interpreter. The judges also clarify the role of the interpreter to the witness and the attorneys. These actions constitute strong evidence of compliance.

Just as corrections recipients should take care to ensure that eligible LEP individuals have the opportunity to reduce the term of their sentence to the same extent that non-LEP individuals do, courts should ensure that LEP persons have access to programs that would give them the equal opportunity to avoid serving a sentence at all.

Example: An LEP defendant should be given the same access as non-LEP defendants to alternative sentencing, such as anger management, batterers’ treatment and intervention, and alcohol abuse counseling, as is given to non-LEP persons in the same circumstances.

Courts have significant contact with the public outside of the courtroom. Providing meaningful access to the legal process for LEP individuals might require more than just providing interpreters in the courtroom. Recipient courts should assess the need for language services all along the process, particularly in areas with high numbers of unrepresented individuals, such as family, landlord-tenant, traffic, and small claims courts.

Example: Only twenty thousand people live in a rural county. The county superior court receives DOJ funds but does not have a budget comparable to that of a more populous urbanized county in the state. Over 1000 LEP Hispanic immigrants have settled in the rural county. The urbanized county also has more than 1000 LEP Hispanic immigrants. Both counties have “how to” materials in English helping unrepresented individuals negotiate the family court processes and providing information for
inmates of domestic violence. The urban county has taken the lead in developing Spanish-language translations of materials that would explain the process. The rural county modifies these slightly with the assistance of family law and domestic violence advocates serving the Hispanic community, and thereby benefits from the work of the urban county. Creative solutions, such as sharing resources across jurisdictions and working with local bar associations and community groups, can help overcome serious financial concerns in areas with few resources.

There may be some instances in which the four-factor analysis of a particular portion of a recipient’s program leads to the conclusion that language services are not currently required. For instance, the four-factor analysis may not necessarily require that a purely voluntary tour of a ceremonial courtroom be given in languages other than English by courtroom personnel, because the relative importance may not warrant such services given the prioritization of the other factors. However, a court may decide to provide such tours in languages other than English given the demographics and the interest in the court. Because the analysis is fact-dependent, the same conclusion may not be appropriate with respect to all tours.

Just as with police departments, courts and/or particular divisions within courts may have more contact with LEP individuals than an assessment of the general population would indicate. Recipients should consider that higher contact level when determining the number or proportion of LEP individuals in the contact population and the frequency of such contact.

Example: A county has very few residents who are LEP. However, many Vietnamese-speaking LEP motorists go through a major freeway running through the county that connects two areas with high populations of Vietnamese-speaking LEP individuals. As a result, the Traffic Division of the county court processes a large number of LEP persons, but it has taken no steps to train staff or provide forms or other language access in the Vietnamese language. The Division may find that it needs to provide key forms or instructions in Vietnamese. It may also find, from talking with community groups, that many older Vietnamese LEP individuals do not read Vietnamese well, and that it should provide oral language services as well. The court may already have Vietnamese-speaking staff competent in interpreting in a different section of the court; it may decide to hire a Vietnamese-speaking employee who is competent in the skill of interpreting; or it may decide that a telephonic interpretation service suffices.

2. Juvenile Justice Programs

DOJ provides funds to many juvenile justice programs to which this Guidance applies. Recipients should consider LEP parents when minor children encounter the legal system. Absent an emergency, recipients are strongly discouraged from using children as interpreters for LEP parents.

Example: A county coordinator for an anti-gang program operated by a DOJ recipient has noticed that increasing numbers of gangs have formed comprised primarily of LEP individuals speaking a particular foreign language. The coordinator may choose to assess the number of LEP youths at risk of involvement in these gangs, so that she can determine whether the program should hire a counselor who is bilingual in the particular language and able to provide other types of language services to the LEP youths. When applying the four factors, recipients encountering juveniles should take into account that certain programs or activities may be even more critical and difficult to access for juveniles than they would be for adults. For instance, although an adult detainee may need some language services to access family members, a juvenile being detained on immigration-related charges who is held by a recipient may need more language services in order to have access to his or her parents.

3. Domestic Violence Prevention/Treatment Programs

Several domestic violence prevention and treatment programs receive DOJ financial assistance and thus must apply this Guidance to their programs and activities. As with all other recipients, the mix of services needed should be determined after conducting the four-factor analysis. For instance, a shelter for victims of domestic violence serving a largely Hispanic area in which many people are LEP should strongly consider accessing qualified bilingual counselors, staff, and volunteers, whereas a shelter that has experienced almost no encounters with LEP persons and serves an area with very few LEP persons may only reasonably need access to a telephonic interpretation service.

Experience, program modifications, and demographic changes may require modifications to the mix over time.

Example: A shelter for victims of domestic violence is operated by a recipient of DOJ funds and located in an area where 15 percent of the women in the service area speak Spanish and are LEP. Seven percent of the women in the service area speak various Chinese dialects and are LEP. The shelter uses competent community volunteers to help translate vital outreach materials into Chinese (which is one written language despite many dialects) and Spanish. The shelter hotline has a menu providing key information, such as location, in English, Spanish, and two of the most common Chinese dialects. Calls for immediate assistance are handled by the bilingual staff. The shelter has one counselor and several volunteers fluent in Spanish and English. Some volunteers are fluent in different Chinese dialects. The shelter works with community groups to access interpreters in the several Chinese dialects that they encounter. Shelter staff train the community volunteers in the sensibilities of domestic violence intake and counseling. Volunteers sign confidentiality agreements. The shelter is looking for a grant to increase its language capabilities despite its tiny budget. These actions constitute strong evidence of compliance.
MAY 28 2009

Mr. David B. Snow, Jr.
Chairman of the Board and Chief Executive Officer
Medco Health Solutions, Inc.
100 Parsons Pond Drive
Franklin Lakes, New Jersey 07417

Reference Number: 06-44385

Dear Mr. Snow:

The U.S. Department of Health and Human Services (HHS), Office for Civil Rights (OCR), has completed its investigation of the above referenced complaint, received by OCR on October 24, 2005, against Medco Health Solutions, Inc. (Medco). The complaint was filed by the complainant on behalf his mother (the affected party) and all limited English proficient (LEP) members of Medco. By “LEP members,” we mean those LEP individuals who are entitled to access Medco’s services through their arrangements with health plan sponsors and other entities that have contracted with Medco. The complaint alleged discrimination on the basis of national origin. Specifically, the complaint alleges that Medco failed to provide LEP members, including the affected party, with meaningful access to mail-order pharmacy services and other pharmacy benefit management services provided by Medco.

Background

OCR conducted its investigation in accordance with Title VI of the Civil Rights Act of 1964 (Title VI), 42 U.S.C. § 2000d et seq., and its implementing regulation at 45 C.F.R. Part 80, which prohibit discrimination on the basis of race, color and national origin. OCR reviewed documentation submitted by the complainant and Medco. OCR also spoke with the complainant and interviewed Medco staff. During the course of the investigation, OCR identified certain concerns relating to Medco’s provision of language assistance services, and discussed these concerns with Medco’s designated representative. Medco’s designated representative indicated that, within Medco, there was a perceived business need to address the issue of language assistance services and expressed an interest in resolving the allegations of the complaint. Thereafter, OCR and Medco agreed to address the issues in the complaint through the implementation of corrective actions. To that end, Medco provided OCR with its written assurance that it is willing to implement a number of measures to strengthen its provision of language assistance services to LEP members with whom Medco directly communicates.

Medco identifies itself as one of the nation’s largest pharmacy benefit managers (PBMs). Medco indicates that, as a PBM, it administers prescription drug benefit plans on behalf of plan sponsor clients, such as private and public employers, health plans, labor unions and government agencies. Medco states that it provides its clients with “core” pharmacy benefit management
services, including third-party claims processing, formulary administration, benefit plan communications and other similar activities. With respect to its mail-order pharmacy operations, Medco’s Annual Report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 describes its mail-order pharmacy operations as the industry’s largest in terms of the number of prescriptions dispensed: Medco’s mail-order pharmacies dispensed 105.8 million prescriptions in 2008. As reported by Medco to OCR, the foreign language most frequently spoken by Medco’s LEP members is Spanish, followed by Chinese.

The complainant indicated that the affected party only speaks and reads Spanish. OCR learned that the affected party is a member of a specific health plan that has contracted with Medco to manage its prescription drug benefit. Under the plan covering the affected party, health plan members may use Medco’s mail-order pharmacy and Medco’s network of retail pharmacies. Medco administers the prescription drug claims of the health plan members. The complainant alleged that Medco discriminates against the affected party (and all LEP members) in a number of ways, including failing to translate important documents or telephone recordings. The complainant alleged that in certain circumstances, Medco calls LEP members and leaves voicemail messages only in English or sends written communications only in English which request that the LEP members take a certain action. According to the complainant, if an LEP member does not take action, because he/she did not understand the request, then this may result in Medco’s cancelling the LEP member’s prescription (re)fill request, which is particularly problematic for an individual trying to manage a chronic condition, such as high blood pressure.

Medco’s Commitments to Improve Service to Limited English Proficient (LEP) Persons

Following the initiation of OCR’s investigation, Medco informed OCR that in late 2008, it instituted a project (referred to as the “Other Than English Language” project), staffed with a core team of senior level Medco employees. Through the phased implementation of certain actions throughout 2009, and the identification of certain goals to be addressed beyond 2009, the project will implement changes to Medco’s systems, processes, policies and procedures, focusing on the Spanish language throughout 2009. Medco indicated that the core team expects that this will be a multi-year project that will continue to work on other languages, in addition to Spanish, after 2009.

In summary, Medco identified to OCR certain actions that it will take to improve Medco’s ability to identify and track LEP members’ language preferences, thus improving staff’s ability to access such information and permitting Medco to ensure that certain written communications are sent, and certain outbound telephone calls are placed, to LEP members in their primary language. OCR learned that the systems, processes, policies and procedures created and implemented by Medco will include an ongoing assessment of which communications must be offered in languages other than English, and which languages are required to be supported.

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1 Medco’s Annual Report indicates that, through its arrangements with networks of retail pharmacies (approximately 60,000 independent and chain retail pharmacies), its specialty pharmacy and its mail-order pharmacies, Medco administered 586 million prescriptions in 2008, serving the needs of more than 60 million people.
OCR also learned that, although Medco continues to have telephonic interpreter services available for over 150 languages other than English, Medco expanded the number of bilingual staff who speak Spanish, and committed to make certain changes to the current telephone systems to improve Medco’s ability to route Spanish-speaking members to such bilingual staff.

Medco also committed to assess the feasibility of methods to improve the provision of notice to LEP members about the availability of language assistance services. To this end, Medco identified to OCR a number of specific initiatives being evaluated, relating to written communications from Medco and Medco’s internet website. Among the initiatives being considered are: including a footer in Spanish on all Medco communications (for example, “para informarse en español llame al 1-800-123-4567”); adding language to Medco’s website; printing certain communications with English on one side and Spanish on the other; and/or the insertion of a Spanish-language notice in certain pharmacy communications, which notice would inform the LEP member that he/she may call Medco for language assistance services.

Medco also indicated that it is developing a process to ensure that Medco staff at call centers and pharmacies, who are either expected to communicate directly with LEP members in a language other than English, or are expected to function as an interpreter with English-speaking Medco staff, are assessed as to their proficiency in that language and, to the extent that they are expected to function as interpreters, their competency at interpreting.

OCR also learned that Medco will monitor the systems and processes that it implements as a result of the “Other Than English Language” project. OCR confirmed that this monitoring will include periodic assessments of the effectiveness of such systems and processes, and that Medco will train all relevant staff on such systems, processes, policies and procedures.

Additionally, Medco agreed that, during the year following the date of this letter, Medco (through its designated representative) will periodically update OCR on significant activities relating to Medco’s implementation of the foregoing measures. OCR agreed to continue to serve as a technical assistance resource throughout that year, as reasonably necessary and as requested by Medco.

**Conclusion**

Based on the above described commitments and actions, OCR has determined that further investigation is not necessary and OCR has closed the case as of the date of this letter.

**Advisements**

OCR’s determination is not intended, nor should it be construed, to cover any issues regarding Medco’s compliance status with Title VI which are not specifically addressed in this letter. It neither covers issues or authorities not specifically addressed herein nor does it preclude future determinations of compliance that are based on subsequent investigations.

Please note that 45 C.F.R. § 80.7(e), provides that no recipient or other person shall intimidate, threaten, coerce, or discriminate against an individual for the purpose of interfering with any
right, or privilege secured by Title VI or its implementing regulation, or because an individual has made a complaint, testified, assisted or participated in an investigation, proceeding or hearing under the Title VI implementing regulation.

Under the Freedom of Information Act, it may be necessary for OCR to release this document and related correspondence and records upon request. In the event OCR receives such a request, we will seek to protect to the extent provided by law, personal information the disclosure of which would constitute an unwarranted invasion of privacy.

We appreciate the cooperation and professionalism extended to OCR by Paul E. DelloRusso, Esq., Assistant Counsel. If you have any questions, please contact Linda C. Colón, Deputy Regional Manager, or me at (212) 264-3313.

Sincerely,

/S/

Michael R. Carter
Regional Manager
Office for Civil Rights
Region II

cc: Daniel C. Walden
Senior Vice President – Corporate Compliance
Officer and Chief Privacy Officer
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